i-SECURE Pomalidomide Risk Management Program

Dear Healthcare Professional,

Pomalidomide is a thalidomide analogue and belongs to the class of immunomodulatory drugs known as IMiDs® compounds.

Pomalidomide is indicated in combination with
Dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

Pomalidomide is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects.

If Pomalidomide is taken during pregnancy, a teratogenic effect of Pomalidomide in humans is expected.

Therefore, Biologix and Celgene have developed a risk management program for the GCC called i-SECURE (ImiDs Strategy and Education for a Controlled Use of Revlimid, Pomalidomide and thalidomidE).

Biologix would like to provide you with the “i-SECURE Pomalidomide Risk Management Program Folder”.

Your folder contains the information and material needed for prescribing and dispensing Pomalidomide, including information about the Pregnancy Prevention Program.

It is a requirement of the i-SECURE program that all healthcare professionals ensure that they have read and understood this folder before prescribing or dispensing Pomalidomide for patients.

Sincerely,

Biologix FZco

i-SECURE At a Glance

Pomalidomide

Prescriber must

- Complete the "Pomalidomide Prescriber Registration Form" to enroll in the *i-SECURE* Program
- Complete a "Pomalidomide Treatment Initiation Form" to register the patient in the *i-SECURE* Program and obtain a Unique Patient Identification Number (UPIN)
- Communicate the benefits and risks of Pomalidomide therapy to the patient
- Counsel the patient on the risks of exposing an unborn baby to Pomalidomide, and what the patient must do to minimize this risk
- Provide the patient with a "Pomalidomide *i-SECURE* Patient Brochure"
- Provide the patient with a completed and signed "Pomalidomide Prescription Authorization Form" with each Pomalidomide prescription
- Perform the required scheduled pregnancy testing for females of childbearing potential prior to every prescription
- Remind the patient of the safe use of Pomalidomide

Pharmacist must

- Complete the "Pomalidomide Pharmacy Registration Form" to enroll in the *i-SECURE* Program
- Provide counseling to each patient and fill the "Education and Counseling Checklist used by the Registered Pharmacy"
- Send the "Pomalidomide Prescription Authorization Form" and "Education and Counseling Checklist" by email to Biologix at pharmacovigilance@blgx.net
- If all details are verified and approved by Biologix, pharmacy will receive a "Dispense Authorization Form" and dispense
    - o No more than a 4-week (28-day) supply of Pomalidomide per prescription for women of childbearing potential
    - o Up to a 12-week (84-day) supply for all other patient risk categories provided it was so approved by Biologix
- For subsequent prescriptions, verify there are 7 days or less since the last pregnancy test occurred.
- For subsequent prescriptions, verify there are 7 days or less remaining of the 28-day cycles on the existing prescription

Warning:

Please be informed that your registration in *i-SECURE* program can be deactivated once any of *i-SECURE* requirements are not met.

In case of incompliance, Biologix has the right to cease collaboration regarding Pomalidomide under *i-SECURE*.

Documents in Pomalidomide *i-SECURE* Risk Management Program Folder

- Pomalidomide *i-SECURE* at a Glance
- Pomalidomide *i-SECURE* Healthcare Professional Information Pack
  - Pomalidomide Prescriber Registration Form
  - Pomalidomide Pharmacy Registration Form
  - Education and Counseling Checklist used by the Registered Pharmacy"
  - Pomalidomide Patient Registration Confirmation Letter
  - Pomalidomide Dispense Authorization Form
- Pomalidomide Treatment Initiation Form
- Pomalidomide Prescription Authorization Form
- Pomalidomide *i-SECURE* Patient Brochure
- Pomalidomide Adverse Event Report
- Pomalidomide Pregnancy Capture Form

Biologix Contact Information:

Address: Algorithm Pharmaceuticals
Zouk Mosbeh, sea road, near Holiday Beach
P.O.Box: 962-11
Beirut- Lebanon
Tel: + 050 222-9-961 Ext 314 or 348
Fax: + 141 222-9-961
E-mail: pharmacovigilance@blgx.net

Salehiya Contact Information:

Ph. Mohammed Waqas
Pharmacovigilance Representative
Salehiya Trading Establishment
E-Mail : m.waqas@salehiya.com
PO Box 991, Riyadh 11421
Kingdom of Saudi Arabia
Tel #+966 1 1464 6955 Ext 362
Fax #+966 1 1463 4362
Mobile #+966 591211197

CODE

i-SECURE
Pomalidomide

At a Glance

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Fax #+966 1 1463 4362
Mobile #+966 591211197

The National Pharmacovigilance and Drug Safety Centre (NPC)
-Fax: 7662-205-11-966+
-Call NPC at 2038222-11-966+, Exts: 23-2334-2354-2353-2356-231740.
-Toll free phone: 8002490000
-E-mail: npc.drug@sfda.gov.sa
-Website: www.sfda.gov.sa/npc

i-SECURE
Pomalidomide Healthcare Professional Information Pack

Contents

1.0 Introduction

Pomalidomide belongs to the class of immunomodulatory drugs known as IMiDs® compounds. IMiDs® compounds are structurally related to Thalidomide, i.e. compounds that have been designed using the Thalidomide structural backbone but with chemical modifications to optimize their immunological and anticancer properties.

Pomalidomide is structurally related to thalidomide, a known human teratogenic substance that causes severe life-threatening birth defects. Pomalidomide induced, in rats and rabbits, malformations similar to those described with thalidomide.
If pomalidomide is taken during pregnancy, a teratogenic effect in humans is expected. Pomalidomide is therefore contraindicated in pregnant women and in Females of Child Bearing Potential (FCBP) unless they adhere to the conditions of the Pomalidomide Pregnancy Prevention Program.

The conditions of the Pomalidomide Pregnancy Prevention Program must be fulfilled for all male and female patients.

2.0 i-SECURE

Pomalidomide will only be available under a special distribution program, called the i-SECURE program. The aims of this program are to:

- Ensure that use and distribution of Pomalidomide are closely monitored and well controlled
  a. Only prescribers registered with i-SECURE can prescribe Pomalidomide
  b. Patients must enroll in the i-SECURE program to receive Pomalidomide
  c. Only pharmacists/pharmacies registered with i-SECURE can dispense Pomalidomide

- Ensure that patients taking Pomalidomide are fully informed about their treatment and – most importantly – that they take all necessary steps to avoid exposing unborn babies to Pomalidomide
  a. Prescribers must inform patients about the likely benefits and potential risks of Pomalidomide therapy, and properly explain how potential risks can be avoided or minimized
  b. Patients must formally agree to fully comply with the requirements of the i-SECURE program, by signing a "Pomalidomide Treatment Initiation Form"
  c. Females of Childbearing Potential (FCBP) are mandated to perform pregnancy tests before taking Pomalidomide and later on with every single dispense (every 4 weeks), including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation.
  d. Prescribers must provide patients a "Pomalidomide patient brochure"

For additional copies of this information pack or further information about i-SECURE or Pomalidomide please contact Biologix on + 961-9-222050, extension 314 or 348.

3.0 i-SECURE: Responsibilities for registered participants

3.1 Prescribers:

1) All prescribers MUST be registered with i-SECURE to prescribe Pomalidomide

a. To register, prescribers must complete a "Pomalidomide Prescriber Registration Form" after receiving this "Pomalidomide Healthcare Professional Information Pack"

b. Complete and sign the "Pomalidomide Prescriber Registration Form" and provide to Biologix

c. For further information about the registration process please contact Biologix on +961-9-222050 extension 314 or 348 or contact your local medical representative

2) Prescribers MUST agree to the following:

a. Provide counseling to each patient:

- Why it is important not to expose unborn babies to Pomalidomide and what patients can do to prevent such exposure
- What i-SECURE registered patients' responsibilities are in this regard
- Advise all patients on Pomalidomide not to donate blood
- Advise all male patients not to donate semen or sperm when taking Pomalidomide
- Advise all patients who are or might be engaged in any sexual activity to adhere to the effective contraception methods
- Advise all FCBP patients not to breast feed if Pomalidomide therapy was initiated post-partum
- Advise all patients not to share Pomalidomide
- Return unused Pomalidomide to the pharmacist

- On the likely benefits and possible side effects of Pomalidomide treatment
  - o How to recognize potentially serious side effects
  - o How to minimize the risk of developing serious side effects
  - o What to do if symptoms of potentially serious side effects develop

b. Prescribe no more than a 4-week (28 day) supply of Pomalidomide per prescription for females of childbearing potential, or a maximum of 12-week (84-day) supply for all other patients

c. Provide each patient with the "Pomalidomide Patient Brochure"

d. Enroll each patient by submitting a completed and signed "Pomalidomide Treatment Initiation Form" for each new patient being prescribed Pomalidomide. This form must be completed by both the prescriber and the patient. The "Pomalidomide Treatment Initiation Form" is a written confirmation that the patient has received and understood information on the safe use of Pomalidomide. This form is to be completed at initiation of treatment for the first time or after there has been a change in the patient's risk category (e.g. Female of childbearing potential changes to female not of childbearing potential)

e. Send the "Pomalidomide Treatment Initiation Form" e.g. by email, to pharmacovigilance@blgx.net or by fax, to Biologix on + 961 9 222141

f. Retain a copy of the "Pomalidomide Treatment Initiation Form" in the patient's file

g. Biologix will then register the patient and forward a "Patient Registration Confirmation Letter" with a "Unique Patient Identification Number" (UPIN) to the prescriber. The UPIN must be written on each new "Pomalidomide Prescription Authorization Form", which must accompany each prescription for that particular patient. The "Pomalidomide Prescription Authorization Form" shows:

- Patient was counseled on safe use of Pomalidomide
- Patient risk category (female of childbearing potential; female NOT of childbearing potential; male)
- Pregnancy test date and result for female of childbearing potential (Prescriptions must be dispensed within a maximum of 7 days after the last negative pregnancy test date)
- Dosing prescribed
- Milligram strength and number of capsules to be dispensed

h. Provide the patient with a completed and signed "Pomalidomide Prescription Authorization Form" with each Pomalidomide prescription. The patient must present this form to the pharmacy, along with his prescription, or the prescriber may send the "Pomalidomide Prescription Authorization Form" with each prescription prescription to the pharmacy

i. Adhere to i-SECURE guidelines when writing a prescription for prescription

3.2 Patients:

a. Patients MUST be enrolled in the i-SECURE program to receive Pomalidomide

1. Each patient (or his/her parent, legal guardian or authorized representative) must complete and sign the "Pomalidomide Treatment Initiation Form"
2. Patients must present the "Pomalidomide Prescription Authorization Form" to the pharmacy, along with their prescription or the prescriber may send the "Pomalidomide Prescription Authorization Form" and the Pomalidomide prescription to the pharmacy

b. Patients MUST agree to comply with all requirements of the i-SECURE program

1. Each patient must take all necessary steps to avoid exposing an unborn baby to Pomalidomide

3.3 Pharmacists:

a. Pharmacies must be registered with i-SECURE in order to dispense Pomalidomide

1. To register, pharmacies must complete and sign a "Pomalidomide Pharmacy Registration Form" after receiving this "Pomalidomide Healthcare Professional Information Pack" and send the completed form to Biologix
2. Biologix will approve dispenses and authorize shipments to the registered pharmacy
3. For further information about the registration process please contact Biologix on +961-9-222050 extension 314 or 348 or your local Biologix medical representative

b. i-SECURE registered pharmacists MUST agree to do the following:

1. Obtain a Pomalidomide prescription and the "Pomalidomide Prescription Authorization Form" and check the "Pomalidomide Prescription Authorization form" for completeness
2. Provide counseling to each patient and fill the "Education and Counseling Check list used by the Registered Pharmacy"
3. Send the signed "Pomalidomide Prescription Authorization Form" and "Education and Counseling Check list" e.g. by email, to pharmacovigilance@blgx.net or by fax, to Biologix on + 961 9 222141
4. Dispense to a patient Pomalidomide as per Biologix approval sent by fax to the pharmacy
5. Dispense no more than a 4-week (28-day) supply of Pomalidomide for FCBP and up to a maximum of 12-week (84-day) supply for all other patient risk categories provided it was so approved by Biologix
6. A new prescription is required for further dispensing
7. For subsequent prescriptions, verify there are 7 days or less since the last pregnancy test occurred.
8. For subsequent prescriptions, verify there are 7 days or less remaining of the 28-day cycles on the existing prescription
9. Biologix has the right to audit pharmacy's compliance with i-SECURE and check stock present at pharmacy

Warning:

Please be informed that your registration in i-SECURE program can be deactivated once any of i-SECURE requirements are not met.
In case of incompliance, Biologix has the right to cease collaboration regarding controlled Pomalidomide under i-SECURE.

4 What registered prescribers must do before prescribing Pomalidomide according to patient risk categories

The i-SECURE segments Pomalidomide patients in different risk categories according to their childbearing potential:

a. Female of childbearing potential

Females who do not meet the below definition of Female NOT of childbearing potential should be classified as FCBP.

b. Female NOT of childbearing potential

1. Females ≥ 50 years old and naturally amenorrhoeic for ≥ 2 years
    - Amenorrhoea following cancer therapy or during breast-feeding does not does not rule out childbearing potential
2. Females that have premature ovarian failure confirmed by a gynecologist
3. Females that have not begun menstruation
4. Females with bilateral salpingo-oophorectomy or hysterectomy
5. Females with XY genotype, Turner's syndrome or uterine agenesis

c. Male

To minimize the risk of a pregnancy occurring under the treatment of Pomalidomide there are different requirements for each of these patient's risk categories

i-SECURE requirements for females of childbearing potential (FCBP)

1. Pregnancy testing

To confirm absence of a pregnancy, FCBP must have a medically supervised negative pregnancy test with a minimum sensitivity of 50 mIU/ml before starting Pomalidomide.

- A medically supervised pregnancy test should be performed during the consultation, when pomalidomide is prescribed, or in the 7 days prior to the visit to the prescriber once the patient had been using effective contraception for at least 4 weeks. The test should ensure that the FCBP patient is not pregnant when she starts treatment with Pomalidomide
- During treatment, a medically supervised pregnancy test should be repeated every 4 weeks, including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation
- The prescriber documents the date and result of each pregnancy test on the "Pomalidomide Prescription Authorization Form"

2. Contraception requirements for females of childbearing potential

- MUST be established on effective contraception for at least 4 weeks before initiating Pomalidomide therapy
- Use simultaneously two reliable methods of contraception simultaneously for 4 weeks before Pomalidomide therapy, during therapy, during dose interruption and until 4 weeks after therapy

There must be no more than 7 days between the dates of the last negative pregnancy test and the dispensing of pomalidomide. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day if not established on effective contraception, the patient should be referred to an appropriately trained Healthcare Professional for contraceptive advice before initiating Pomalidomide treatment.

3. Examples of effective methods of contraception

a. Highly effective methods

- Intra Uterine Device (IUD)
- Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel)
- Tubal ligation
- Partner's vasectomy

b. Effective barrier methods

- Male condom
- Diaphragm
- Cervical cap

Contraceptive methods must include: At least 1 highly effective method AND 1 additional effective barrier method used at the same time.

Hormonal contraception should be initiated 4 weeks before starting Pomalidomide treatment.

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking Pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended.

Advise patient that if a pregnancy does occur whilst she is receiving Pomalidomide, she must stop treatment immediately and inform her doctor immediately.

4. In the event of pregnancy whilst on treatment with Pomalidomide

- Stop treatment with Pomalidomide
- Refer the patient to a Gynecologist/Obstetrician experienced in reproductive toxicity
- Complete the "Pomalidomide Pregnancy Capture Form" and send it immediately to Biologix and/or Celgene at the numbers/Addresses stated in the "Pomalidomide Pregnancy Capture Form"
- Notify immediately Biologix at 222050-9-961+ ext. 348/314 or Salehiya at:

  Ph. Mohammed Waqas-Pharmacovigilance Representative-Salehiya Trading Establishment
  E-Mail : m.waqas@salehiya.com - PO Box 991, Riyadh 11421 - Kingdom of Saudi Arabia
  Tel #+966 1 1464 6955 Ext 362 Fax #+966 1 1463 4362 Mobile #+966 591211197

  Biologix will wish to follow-up about the progress of all pregnancies occurring under Pomalidomide treatment

i-SECURE requirements for females not of childbearing potential

- Provide counseling as described in section 3.1.2
- Treating Physicians are advised to refer their patient for a gynecological opinion if at all unsure as to whether a woman meets the criteria for being of a female NOT of childbearing potential

i-SECURE requirements for males

Traces of Pomalidomide are present in semen, therefore:

- Male patients should practice complete abstinence or use condoms during sexual intercourse with a pregnant female or a female of childbearing potential throughout the duration of treatment, during dose interruption and for 4 weeks after cessation of treatment if their partner is not established on suitable contraception (even if the male patient has undergone vasectomy)
- Male patients must not donate semen or sperm during therapy including dose interruptions and for 4 weeks following the discontinuation of Pomalidomide

Male patients should be instructed that if their partner becomes pregnant whilst they take Pomalidomide or shortly after the patient stopped Pomalidomide treatment, he should inform his doctor immediately.
Inform your patient which are the effective contraceptive methods that his female partner can use.

5.0 Writing subsequent Pomalidomide prescriptions

When a patient requires a new prescription, simply record the UPIN on the “Pomalidomide Prescription Authorization Form” which should accompany the Pomalidomide prescription and forward it to Biologix

6.0 Reporting of Adverse Events

The safe use of Pomalidomide is of paramount importance. As part of the ongoing safety monitoring, Biologix wish to learn of Adverse Events that have occurred during the use of Pomalidomide.

Biologix reports adverse events to Celgene Global Drug Safety & Risk Management in accordance to the Pharmacovigilance Agreement.

For reporting an Adverse Event or a pregnancy, please contact Biologix at + 222050-9-961 ext. 314 or 348 or Salehiya at: Ph. Mohammed Waqas-Pharmacovigilance Representative - Salehiya Trading Establishment - E-Mail : m.waqas@salehiya.com - PO Box 991, Riyadh 11421- Kingdom of Saudi Arabia - Tel #+966 1 1464 6955 Ext 362 Fax #+966 1 1463 4362 - Mobile #+966 591211197 or fill in the "i-SECURE Adverse Event Report Form

7.0 Salehiya Contact Details

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8.0 i-SECURE Patient Brochure

Please refer to the "Pomalidomide Patient Brochure" included in the end of this folder.

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- Advise all patients on Pomalidomide not to donate blood
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- Advise all FCBP patients not to breast feed if Pomalidomide therapy was initiated post-partum
- Advise all patients not to share Pomalidomide
- Return unused Pomalidomide to the pharmacist

- On the likely benefits and possible side effects of Pomalidomide treatment
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  - o How to minimize the risk of developing serious side effects
  - o What to do if symptoms of potentially serious side effects develop

b. Prescribe no more than a 4-week (28 day) supply of Pomalidomide per prescription for females of childbearing potential, or a maximum of 12-week (84-day) supply for all other patients

c. Provide each patient with the "Pomalidomide Patient Brochure"

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f. Retain a copy of the "Pomalidomide Treatment Initiation Form" in the patient's file

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- Milligram strength and number of capsules to be dispensed

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i. Adhere to i-SECURE guidelines when writing a prescription for prescription

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2. Patients must present the "Pomalidomide Prescription Authorization Form" to the pharmacy, along with their prescription or the prescriber may send the "Pomalidomide Prescription Authorization Form" and the Pomalidomide prescription to the pharmacy

b. Patients MUST agree to comply with all requirements of the i-SECURE program

1. Each patient must take all necessary steps to avoid exposing an unborn baby to Pomalidomide

3.3 Pharmacists:

a. Pharmacies must be registered with i-SECURE in order to dispense Pomalidomide

1. To register, pharmacies must complete and sign a "Pomalidomide Pharmacy Registration Form" after receiving this "Pomalidomide Healthcare Professional Information Pack" and send the completed form to Biologix
2. Biologix will approve dispenses and authorize shipments to the registered pharmacy
3. For further information about the registration process please contact Biologix on +961-9-222050 extension 314 or 348 or your local Biologix medical representative

b. i-SECURE registered pharmacists MUST agree to do the following:

1. Obtain a Pomalidomide prescription and the "Pomalidomide Prescription Authorization Form" and check the "Pomalidomide Prescription Authorization form" for completeness
2. Provide counseling to each patient and fill the "Education and Counseling Check list used by the Registered Pharmacy"
3. Send the signed "Pomalidomide Prescription Authorization Form" and "Education and Counseling Check list" e.g. by email, to pharmacovigilance@blgx.net or by fax, to Biologix on + 961 9 222141
4. Dispense to a patient Pomalidomide as per Biologix approval sent by fax to the pharmacy
5. Dispense no more than a 4-week (28-day) supply of Pomalidomide for FCBP and up to a maximum of 12-week (84-day) supply for all other patient risk categories provided it was so approved by Biologix
6. A new prescription is required for further dispensing
7. For subsequent prescriptions, verify there are 7 days or less since the last pregnancy test occurred.
8. For subsequent prescriptions, verify there are 7 days or less remaining of the 28-day cycles on the existing prescription
9. Biologix has the right to audit pharmacy's compliance with i-SECURE and check stock present at pharmacy

Warning:

Please be informed that your registration in i-SECURE program can be deactivated once any of i-SECURE requirements are not met.
In case of incompliance, Biologix has the right to cease collaboration regarding controlled Pomalidomide under i-SECURE.

4 What registered prescribers must do before prescribing Pomalidomide according to patient risk categories

The i-SECURE segments Pomalidomide patients in different risk categories according to their childbearing potential:

a. Female of childbearing potential

Females who do not meet the below definition of Female NOT of childbearing potential should be classified as FCBP.

b. Female NOT of childbearing potential

1. Females ≥ 50 years old and naturally amenorrhoeic for ≥ 2 years
    - Amenorrhoea following cancer therapy or during breast-feeding does not does not rule out childbearing potential
2. Females that have premature ovarian failure confirmed by a gynecologist
3. Females that have not begun menstruation
4. Females with bilateral salpingo-oophorectomy or hysterectomy
5. Females with XY genotype, Turner's syndrome or uterine agenesis

c. Male

To minimize the risk of a pregnancy occurring under the treatment of Pomalidomide there are different requirements for each of these patient's risk categories

i-SECURE requirements for females of childbearing potential (FCBP)

1. Pregnancy testing

To confirm absence of a pregnancy, FCBP must have a medically supervised negative pregnancy test with a minimum sensitivity of 50 mIU/ml before starting Pomalidomide.

- A medically supervised pregnancy test should be performed during the consultation, when pomalidomide is prescribed, or in the 7 days prior to the visit to the prescriber once the patient had been using effective contraception for at least 4 weeks. The test should ensure that the FCBP patient is not pregnant when she starts treatment with Pomalidomide
- During treatment, a medically supervised pregnancy test should be repeated every 4 weeks, including 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation
- The prescriber documents the date and result of each pregnancy test on the "Pomalidomide Prescription Authorization Form"

2. Contraception requirements for females of childbearing potential

- MUST be established on effective contraception for at least 4 weeks before initiating Pomalidomide therapy
- Use simultaneously two reliable methods of contraception simultaneously for 4 weeks before Pomalidomide therapy, during therapy, during dose interruption and until 4 weeks after therapy

There must be no more than 7 days between the dates of the last negative pregnancy test and the dispensing of pomalidomide. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day if not established on effective contraception, the patient should be referred to an appropriately trained Healthcare Professional for contraceptive advice before initiating Pomalidomide treatment.

3. Examples of effective methods of contraception

a. Highly effective methods

- Intra Uterine Device (IUD)
- Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel)
- Tubal ligation
- Partner's vasectomy

b. Effective barrier methods

- Male condom
- Diaphragm
- Cervical cap

Contraceptive methods must include: At least 1 highly effective method AND 1 additional effective barrier method used at the same time.

Hormonal contraception should be initiated 4 weeks before starting Pomalidomide treatment.

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking Pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended.

Advise patient that if a pregnancy does occur whilst she is receiving Pomalidomide, she must stop treatment immediately and inform her doctor immediately.

4. In the event of pregnancy whilst on treatment with Pomalidomide

- Stop treatment with Pomalidomide
- Refer the patient to a Gynecologist/Obstetrician experienced in reproductive toxicity
- Complete the "Pomalidomide Pregnancy Capture Form" and send it immediately to Biologix and/or Celgene at the numbers/Addresses stated in the "Pomalidomide Pregnancy Capture Form"
- Notify immediately Biologix at 2038222-11-966+, Exts: 2340-2334-2354-2353-2356-2317 or Salehiya at: Ph. Mohammed Waqas-Pharmacovigilance Representative-Salehiya Trading Establishment - E-Mail : m.waqas@salehiya.com - PO Box 991, Riyadh 11421 - Kingdom of Saudi Arabia - Tel #+966 1 1464 6955 Ext 362 Fax #+966 1 1463 4362 Mobile #+966 591211197

  Biologix will wish to follow-up about the progress of all pregnancies occurring under Pomalidomide treatment

i-SECURE requirements for females not of childbearing potential

- Provide counseling as described in section 3.1.2
- Treating Physicians are advised to refer their patient for a gynecological opinion if at all unsure as to whether a woman meets the criteria for being of a female NOT of childbearing potential

i-SECURE requirements for males

Traces of Pomalidomide are present in semen, therefore:

- Male patients should practice complete abstinence or use condoms during sexual intercourse with a pregnant female or a female of childbearing potential throughout the duration of treatment, during dose interruption and for 4 weeks after cessation of treatment if their partner is not established on suitable contraception (even if the male patient has undergone vasectomy)
- Male patients must not donate semen or sperm during therapy including dose interruptions and for 4 weeks following the discontinuation of Pomalidomide

Male patients should be instructed that if their partner becomes pregnant whilst they take Pomalidomide or shortly after the patient stopped Pomalidomide treatment, he should inform his doctor immediately.
Inform your patient which are the effective contraceptive methods that his female partner can use.

5.0 Writing subsequent Pomalidomide prescriptions

When a patient requires a new prescription, simply record the UPIN on the “Pomalidomide Prescription Authorization Form” which should accompany the Pomalidomide prescription and forward it to Biologix

6.0 Reporting of Adverse Events

The safe use of Pomalidomide is of paramount importance. As part of the ongoing safety monitoring, Biologix wish to learn of Adverse Events that have occurred during the use of Pomalidomide.

Biologix reports adverse events to Celgene Global Drug Safety & Risk Management in accordance to the Pharmacovigilance Agreement.

For reporting an Adverse Event or a pregnancy, please contact Biologix at 2038222-11-966+, Exts: 2340-2334-2354-2353-2356-2317 or fill in the "i-SECURE Adverse Event Report Form

7.0 Contact Details

Salehiya:
Ph. Mohammed Waqas
Pharmacovigilance Representative
Salehiya Trading Establishment
E-Mail : m.waqas@salehiya.com
PO Box 991, Riyadh 11421
Kingdom of Saudi Arabia
Tel #+966 1 1464 6955 Ext 362
Fax #+966 1 1463 4362
Mobile #+966 591211197

Biologix:
Address: Algorithm Pharmaceuticals
Zouk Mosbeh, sea road, near Holiday Beach
P.O.Box: 962-11
Beirut- Lebanon
Tel: + 222-9-961 050; Ext: 314 or 348
Fax: + 141 222-9-961
E-mail: pharmacovigilance@blgx.net

The National Pharmacovigilance and Drug Safety Centre (NPC)
-Fax: 7662-205-11-966+
-Call NPC at 2038222-11-966+, Exts: 2340-2334-2354-2353-2356-2317.
-Toll free phone: 8002490000
-E-mail: npc.drug@sfda.gov.sa
-Website: www.sfda.gov.sa/npc

8.0 i-SECURE Patient Brochure

Please refer to the "Pomalidomide Patient Brochure" included in the end of this folder.

i-SECURE
Pomalidomide

Prescriber Registration Form

This form will need to be completed by physicians to register into the *i-SECURE* program before prescribing Pomalidomide. This is a one time registration.

Please fill out in capital letters

Prescriber Details

First Name:		
Last Name:		
Specialty:		
Practitioner Registration/License Number:		
Hospital Name and Address:		
E-mail Address:		
Telephone:		Fax:

I have read and understood the *i-SECURE* Healthcare Professional Information Pack, explaining the risks for patients receiving Pomalidomide, particularly the risk of fetal exposure, and I shall comply with the requirements of the *i-SECURE* program.

Signature _____ Date: | | | | | | | | |

D D M M Y Y Y Y

Please provide to Salehiya or Biologix before prescribing Pomalidomide

Salehiya:
Ph. Mohammed Waqas - Pharmacovigilance Representative
Salehiya Trading Establishment - E-Mail : m.waqas@salehiya.com
PO Box 991, Riyadh 11421 - Kingdom of Saudi Arabia
Tel #+966 1 1464 6955 Ext 362 - Fax #+966 1 1463 4362 - Mobile #+966 591211197

Biologix:
Email : Pharmacovigilance@blgx.net
Fax : +961 9 222141

CODE

i-SECURE

Pharmacy Registration Form

Pomalidomide

This form will need to be completed by pharmacist to register into the Pomalidomide Risk Management Program before dispensing Pomalidomide to patients. This is a one time registration.

Please fill out in capital letters

Pharmacist Details (Head Pharmacist)

First Name:		
Last Name:		
Dispensing License Number:		
Pharmacy Address:		
Telephone:		Fax*:
E-mail Address:		
***The fax number will be used by Biologix to authorize Revlimid prescriptions**		

I have read and understood the Pomalidomide *i-SECURE* Healthcare Professional Information Pack explaining the risks for patients receiving Pomalidomide, particularly the risk of fetal exposure.

I agree to implement the following *i-SECURE* risk minimization procedures when dealing with prescriptions for Pomalidomide:

1.	All pharmacists dispensing Pomalidomide will have read and understood the i-SECURE Healthcare Professional Information Pack.
2.	Pomalidomide will be dispensed only if: - The prescription is accompanied by a completed Pomalidomide Prescription Authorization Form AND - After receiving authorization from Biologix AND - Will dispense subsequent prescriptions, after verification that there are a maximum of 7 days or less since the last pregnancy test occurred. - Will dispense no more than a 4-week (28 day) supply of Pomalidomide per prescription to women of childbearing potential, or a maximum of 12-week (84-day) supply for all other patient's risk categories provided it was so approved by Biologix - Will dispense subsequent prescriptions, after verification that there are 7 days or less remaining of the 28-day cycles on the existing prescription
3.	Compliance with these procedures will be subject to audits by Biologix

Warning:

Please be informed that your registration in *i-SECURE* program can be deactivated once any of *i-SECURE* requirements are not met
In case of incompliance, Biologix has the right to cease collaboration regarding Pomalidomide under *i-SECURE.*

Signature _____ Date: | | | | | | | | |

D D M M Y Y Y Y

Please provide this form to Biologix before dispensing Pomalidomide to Patients. A copy must be filed at the pharmacy
Email : Pharmacovigilance@blgx.net
Fax : +961 9 222141

i-SECURE

Patient Registration Confirmation Letter

Pomalidomide

To:	
Date:	

Biologix FZCO hereby confirm registration of the patient _____ in the *i-SECURE* Risk Management Program

Mr/Ms _____ has been given UPIN _____

If you have any questions about the i-SECURE program, please contact Biologix at 222050-9-961+ Ext 314 or 348 or Salehiya at: Ph. Mohammed Waqas-Pharmacovigilance Representative - Salehiya Trading Establishment - E-Mail : m.waqas@salehiya.com - PO Box 991, Riyadh 11421- Kingdom of Saudi Arabia - Tel #+966 1 1464 6955 Ext 362 Fax #+966 1 1463 4362 - Mobile #+966 591211197 or fill in the “i-SECURE Adverse Event Report Form

Dispense Authorization Form

Pomalidomide

BIOLOGIX FZCO hereby approve the release of Pomalidomide capsules to:

Patient Name: .....

UPIN: .....

Prescribed dose: ..... mg/day

Duration: ..... days

Quantity of capsules to be dispensed: ..... caps

Box(es): ..... box(es) Signature: .....

Pharmacy name: .....

Date: .....

i-SECURE Treatment Initiation Form

Pomalidomide

This form must be completed for each patient prior to the initiation of their Pomalidomide treatment and in the case of a change in the patient's risk category. Retain a copy of this form with their medical records. The aim of the "Treatment Initiation Form" is to protect patients and any possible unborn children by ensuring that patients are fully informed on the safe use of Pomalidomide.

Please fill the two pages in capital letters

With this Treatment Initiation Form:
- The prescribing physician confirms individual counseling for the signing patient receiving Pomalidomide
- The patient confirms to fully comply with all requirements of the *i-SECURE* program

Patient Details

Name: (First Name, Middle Name, Family Name)			
Date of birth	_____ DD _____ MM _____ YYYY		
Counseling Date	_____ DD _____ MM _____ YYYY		
City:		Phone Number:	

Patient will receive Pomalidomide to treat

☐ Multiple Myeloma

☐ Other (please specify):.....

.....

Status of Patient

☐ Female of Childbearing Potential

Females who do not meet the below definition of Female NOT of childbearing potential should be classified as FCBP.

☐ Female of Non-Childbearing Potential

1. Females ≥ 50 years old and naturally amenorrhoeic for ≥ 2 years
   - Amenorrhoea following cancer therapy does not rule out childbearing potential
2. Females that have premature ovarian failure confirmed by a gynecologist
3. Females that have not begun menstruation
4. Females with bilateral salpingo-oophorectomy or hysterectomy
5. Females with XY genotype, Turner's syndrome or uterine agenesis

☐ Male

POM-TIFe-v. 1.0

Treatment Initiation Form

Pomalidomide

Prescriber

I have fully explained to the patient named above, the nature, purpose and risks of the treatment associated with Pomalidomide, particularly the special precautions required to prevent the exposure of an unborn child to Pomalidomide in accordance to the *i-SECURE* Program.

The following material has been provided to the patient (please tick box):

☐ *i-SECURE* Patient Brochure

Prescriber Name: _____
(First/Middle/Family Names)

Hospital / Centre _____

Prescriber Signature _____ Date (DD/MM/YYYY) _____

Patient

I confirm that I have received information on the likely benefits and possible side effects of Pomalidomide treatment, including why it is important not to expose unborn babies to Pomalidomide and what I can do to prevent such exposure.

I further confirm that I understand and will comply with the requirements of the *i-SECURE* Program, and I agree that my doctor can initiate my treatment with Pomalidomide.

Patient name _____

Signature _____ Date (DD/MM/YYYY) _____

Upon receipt of this form, Biologix will register the patient and forward to the prescriber a Unique Patient Identifier Number (UPIN). The UPIN must be written on each new Pomalidomide Prescription Authorization Form, which must accompany each prescription for this patient.

POM-TIFe-v. 1.0

طلب المباشرة بالعلاج

i-SECURE

Pomalidomide

يجب ملء هذا الطلب لكل مريض قبل المباشرة بعلاج Pomalidomide وفي حال تغيير في فئة المريض. يُرجى الاحتفاظ بنسخة عن هذا الطلب في ملفّ المريض الطبي. يهدف هذا الطلب إلى حماية المريض، او الجنين في حال الحمل، من خلال إطلاع المريض بشكل كامل على الاستخدام الآمن لـ Pomalidomide.

يُرجى ملء الطلب بخط واضح

من خلال طلب المباشرة بالعلاج هذا:
-يؤكّد الطبيب المعالج أنّه سيشرح شخصيًّا للمريض الموقّع سبل الوقاية عند تناول Pomalidomide.
-يؤكّد المريض أنّه سيمتثل تمامًا لشروط برنامج i-SECURE كافةً.

المعلومات عن المريض:

الاسم الثلاثي:			
تاريخ الولادة: (اليوم/الشهر/السنة)			_____ _____ _____
تاريخ الاستشارة: (اليوم/الشهر/السنة)			_____ _____ _____
المدينة:		رقم الهاتف:	

سيتلقّى المريض علاجًا بـ Pomalidomide لمعالجة:

☐ المايلوما المتعدّدة (Multiple Myeloma)
☐ حالات أخرى (يُرجى التحديد)

_____

وضع المريض:

☐ امرأة قادرة على الانجاب
☐ امرأة غير قادرة على الانجاب
☐ رجل

الطبيب

لقد شرحت بشكل كاف إلى المريض الوارد اسمه أعلاه طبيعة العلاج بواسطة Pomalidomide، وهدفه، ومخاطره، لا سيّما طرق الوقاية الخاصة المطلوبة لعدم تعريض أي جنين لمفاعيل Pomalidomide وفق برنامج i-SECURE.

تمّ تأمين المستندات التالية إلى المريض (يُرجى وضع إشارة اذا اعطي للمريض):

☐ كتيّب المريض حول برنامج i-SECURE

إسم الطبيب الثلاثي _____

المستشفى / المركز _____

توقيع الطبيب _____ التاريخ (اليوم/الشهر/السنة) _____

طلب المباشرة بالعلاج

i-SECURE

Pomalidomide

المريض

أؤكّد أنّني حصلت على المعلومات حول المنافع والآثار الجانبية الضّارة المحتملة لعلاج Pomalidomide، بما في ذلك أهميّة عدم تعريض أي جنين لـ Pomalidomide، وما يُمكنني فعله لتجنّب تعريض الجنين للدواء.

كما أؤكّد أنّني فهمت وأنّني أمتثل لشروط برنامج i-SECURE، وأوافق على أن يباشر طبيبي بوصف علاج Pomalidomide، لي.

التوقيع: _____ التاريخ (اليوم/الشهر/السنة): _____

عند الحصول على هذا الطلب، تبدأ بايولوجيكس بتسجيل المريض وتُرسل إلى الطبيب رقم تعريفي فريد لكل مريض (UPIN). يجب تدوين الـ UPIN على كل طلب إذن جديد بوصف Pomalidomide، الذي يجب أن يُرافق كل وصفة لهذا المريض.

POM-TIFa-v. 1.0

i-SECURE

Prescription Authorization Form

Pomalidomide

A newly completed copy of this form MUST accompany every Pomalidomide prescription. Completion of this form is mandatory for ALL patients.

Please fill the two pages in capital letters

Patient Details

First Name:	
Last Name:	
Unique Patient Identification Number:	
Date of birth:	_____ _____ _____ DD MM YYYY
Dose prescribed:	_____mg/day _____ days

Patient Risk Category (tick one), and answer accordingly

☐ Female of non-childbearing potential		
☐ Male		
	The patient has been counseled about the teratogenic potential of treatment with Pomalidomide and understands the need to use a condom if involved in sexual activity with a pregnant woman or a woman of childbearing potential who is not using an effective method of contraception during therapy (including dose interruptions), and for 4 weeks after treatment cessation.	Yes ☐ No ☐
☐ Female of childbearing potential		
	The patient has been counseled about the teratogenic potential of treatment with Pomalidomide, the need to avoid pregnancy and has been using simultaneously two reliable methods of contraception for at least 4 weeks prior to treatment initiation, during therapy (including dose interruptions) and for at least 4 weeks after treatment cessation?	Yes ☐ No ☐
	Last pregnancy test date (DD/MM/YYYY)	
	Last pregnancy test result negative?	Yes ☐ No ☐

Prescription Authorization Form

Pomalidomide

Prescriber

I have read and understood the *i-SECURE* Healthcare Professional Information Pack, and confirm that the patient has signed a Pomalidomide Treatment Initiation Form.

Prescriber Name _____

Prescriber Signature _____ Date (DD/MM/YYYY) _____

Pharmacy Confirmation

Note to pharmacist: the date of the prescription must match the date on this Pomalidomide Prescription Authorization Form. Do not dispense to FCBP unless the pregnancy test is negative and was performed within a maximum 7 days of the prescription date.

I am satisfied that the "Pomalidomide Prescription Authorization Form" has been completed fully and that I have read and understood the *i-SECURE* Healthcare Professional Information Pack

Strength: _____ Duration: _____

Quantity of capsules to be dispensed: _____

Pharmacist Name: _____

Pharmacy Name: _____

Signature _____ Date (DD/MM/YYYY) _____

i-SECURE

Education and Counseling Checklist Used by the Registered Pharmacy

Pomalidomide

The following checklist must be completed by an i-SECURE registered pharmacy. Please use the checklist that applies to the patient risk category written on the Prescription Authorisation Form.

Checklist for Females of Childbearing Potential

I counseled patients on:

- ☐ Potential fetal harm
- ☐ Using 2 forms of effective birth control at the same time or abstaining from heterosexual sexual intercourse
- ☐ Continuation of 2 forms of birth control if therapy is interrupted and for 4 weeks after therapy is discontinued
- ☐ Obtain a pregnancy test repeated every 4 weeks in females with regular menstrual cycles.
- ☐ The need to stop taking Pomalidomide immediately if suspected to be pregnant and to call their healthcare provider immediately. Female partners of male patients taking Pomalidomide must call their healthcare provider immediately in case of suspected pregnancy
- ☐ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ☐ Not sharing medication
- ☐ Not donating blood while taking Pomalidomide and for 4 weeks after stopping Pomalidomide
- ☐ Not to break, chew, or open Pomalidomide capsules
- ☐ Instructions on Pomalidomide dose and administration: Dose _____ # of Capsules Dispensed _____

Checklist for Females NOT of Childbearing Potential

I counseled patients on:

- ☐ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ☐ Not sharing medication
- ☐ Not donating blood while taking Pomalidomide and for 4 weeks after stopping Pomalidomide
- ☐ Not to break, chew, or open Pomalidomide capsules
- ☐ Instructions on Pomalidomide dose and administration: Dose _____ # of Capsules Dispensed _____

Checklist for Males

I counseled patients on:

- ☐ Potential fetal harm and contraception (wearing a latex condom when engaging in sexual intercourse with a pregnant woman or a female of childbearing potential not using effective contraception) during therapy (including dose interruptions) and for at least 4 weeks after treatment cessation.
- ☐ Possible side effects due to neutropenia, thrombocytopenia, deep vein thrombosis, and pulmonary embolism
- ☐ Not sharing medication
- ☐ Not donating blood while taking Pomalidomide and for 4 weeks after stopping Pomalidomide
- ☐ Not to break, chew, or open Pomalidomide capsules
- ☐ Instructions on Pomalidomide dose and administration: Dose _____ # of Capsules Dispensed _____

DO NOT dispense or ship Pomalidomide to a patient unless all the following are done:

- ☐ You have counseled the patient
- ☐ You have obtained a dispense authorization from Biologix
- ☐ The i-SECURE patient brochure is provided to the patient
- ☐ You confirm that for subsequent prescriptions, that there are at maximum 7 days or less remaining of the 28-day cycles on the existing prescription
- ☐ You confirm for subsequent prescriptions, that there are at maximum 7 days or less since the last pregnancy test occurred

Please send this form to Biologix at pharmacovigilance@blgx.net

i-SECURE
Pomalidomide Patient Brochure

Introducing i-SECURE

Your Doctor intends to prescribe Pomalidomide for you.

Pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child. Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.

To avoid fetal exposure, Pomalidomide is available only under a special distribution program called i-SECURE.

The i-SECURE program is designed to ensure that Pomalidomide therapy is always prescribed and taken in the recommended way.

Key features of the program:

- Only physicians registered with i-SECURE can prescribe Pomalidomide
- Only pharmacists/pharmacies registered with i-SECURE can dispense Pomalidomide
- Only patients who have been formally enrolled in the i-SECURE program can receive Pomalidomide

To enroll, patients must sign a “Pomalidomide Treatment Initiation Form” and agree to fully comply with all requirements of the i-SECURE program.

IMPORTANT TO REMEMBER:

Pomalidomide may cause birth defects or death to unborn babies.

Content

Special i-SECURE Requirements for Females who are Able to Become Pregnant

Include:

Females who do not meet the below definition of Female NOT of childbearing potential should be classified as Females of childbearing potential (FCBP).

Females NOT of childbearing potential are:

1. Females ≥ 50 years old and naturally amenorrhoeic for ≥ 2 years
   - Amenorrhoea following cancer therapy does not rule out childbearing potential
2. Females that have premature ovarian failure confirmed by a gynecologist
3. Females that have not begun menstruation
4. Females with bilateral salpingo-oophorectomy or hysterectomy
5. Females with XY genotype, Turner's syndrome or uterine agenesis

Important: do NOT become pregnant:

- During the four weeks before starting Pomalidomide treatment
- While taking Pomalidomide
- During any interruption in Pomalidomide treatment
- During the four-week period following the conclusion of your Pomalidomide treatment

Before starting treatment:

1. You must sign a "Pomalidomide Treatment Initiation Form", agreeing not to become pregnant while taking Pomalidomide and following all requirements within i-SECURE
2. You must use two reliable methods of birth control (contraception) at the same time 4 weeks before starting Pomalidomide treatment. Refer below for examples of effective methods of contraception:
   - Highly effective methods
     - Intra Uterine Device (IUD)
     - Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel)
     - Tubal ligation
     - Partner's vasectomy

- Effective barrier methods
  - Male condom
  - Diaphragm
  - Cervical cap

Contraceptive methods must include: At least 1 highly effective method AND 1 additional effective barrier method used at the same time.

3. You must have a medically supervised pregnancy test done during your consultation with the doctor, when Pomalidomide is prescribed, or in the 7 days prior to the dispensing by the pharmacist once you had been using effective contraception for at least 4 weeks. The test should ensure that you are not pregnant when you start treatment with Pomalidomide
4. You must agree to not breastfeed or donate blood
5. You must agree to never share your Pomalidomide capsules
6. You must agree to return unused Pomalidomide capsules to your pharmacist

During treatment and dose interruptions:

1. You must continue to use two reliable methods of birth control (contraception) at the same time during treatment and during any interruption in Pomalidomide treatment
2. You must also undergo regular medically supervised pregnancy tests every four weeks during treatment
3. You must not breastfeed or donate blood
4. Never share your Pomalidomide capsules

Note: If you miss a period, experience any abnormality in menstrual bleeding, suspect you are pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Stop Pomalidomide immediately
- Tell your doctor
- Have a pregnancy test

Pomalidomide

For four weeks after treatment:

1. You must continue to use two reliable methods of birth control (contraception) at the same time
2. You must not breastfeed or donate blood
3. Never share your Pomalidomide capsules
4. Return unused Pomalidomide capsules to your pharmacist
5. You must undergo a medically supervised pregnancy test 4 weeks after discontinuation of Pomalidomide therapy

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Tell your doctor
- Have a pregnancy test

i-SECURE Requirements for Females who are NOT Able to Become Pregnant

Include:

- Females ≥ 50 years old and naturally amenorrheic for ≥ 2 years
  - Amenorrhea following cancer therapy does not rule out childbearing potential
- Females that have premature ovarian failure confirmed by a gynecologist
- Females with bilateral salpingo-oophorectomy or hysterectomy
- Females with XY genotype, Turner's syndrome or uterine agenesis

Pomalidomide

Before starting treatment:

1. You must sign a "Pomalidomide Treatment Initiation Form", indicating that you are not pregnant and do not have the ability to have children and will follow all requirements within i-SECURE
2. You must agree to not donate blood
3. You must agree to never share your Pomalidomide capsules
4. You must agree to return unused Pomalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1. You must not donate blood
2. Never share your Pomalidomide capsules

For four weeks after treatment:

1. You must not donate blood
2. Return unused Pomalidomide capsules to your pharmacist

i-SECURE Requirements for Male Patients

Before starting treatment:

1. Pomalidomide is present in semen. You must sign a "Pomalidomide Treatment Initiation Form", agreeing to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy) not using highly effective method of contraception and will follow all requirements within i-SECURE including the following:
   - You must agree to not donate blood, sperm or semen
   - You must agree to never share your Pomalidomide capsules
   - You must agree to return unused Pomalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1 You must use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy) not using highly effective methods
2. You must tell your doctor if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your part ner may be pregnant
3. You must not donate blood, sperm or semen
4. Never share your Pomlidomide capsules

For four weeks after treatment:

1. You must continue to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy) not using highly effective methods
2. You must tell your doctor if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant
3. You must not donate blood, sperm or semen
4. Never share your Pomlidomide capsules
5. Return unused Pomlidomide capsules to your pharmacist

Special Warnings and Precautions

Low white blood cells (neutropenia) and low platelets (thrombocytopenia).

Pomlidomide causes low white blood cells and low platelets in most patients. You may need a blood transfusion or certain medicines if your blood counts drop too low. Complete blood counts should be monitored at baseline, weekly for the first 8 weeks and monthly thereafter. A dose modification may be required.

Pomalidomide

A higher chance for blood clots in your veins and lungs.

Call your healthcare provider or get medical help right away if you get any of these signs or symptoms:

a. shortness of breath
b.chest pain
c. arm or leg swelling

Possible side effects of Pomalidomide

Pomlidomide may cause serious side effects.
Serious skin reactions. Serious skin reactions can happen with Pomlidomide
Call your healthcare provider right away if you have any skin reaction while taking Pomlidomide.

Tumor lysis syndrome. Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the breakdown products of dying cancer cells and may include the following: changes to blood chemistry, high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.

Common side effects of skin Pomalidomide are:

Diarrhea
Nausea
Constipation
Rash
Tiredeness
Bone pain

These are not all the possible side effects of Pomalidomide. Tell your healthcare provider about any side effect that bothers you or that does not go away

How should you take Pomalidomide?

Take Pomalidomide exactly as prescribed and follow all the instructions of the i-SECURE program.

Pomalidomide should not be taken with food.(at least 2 hours before or 2 hours after a meal)

Do not open the Pomalidomide capsules or handle them any more than needed. If you touch a broken Pomalidomide capsule or the medicine in the capsule, wash the area of your body with soap and water

If you miss a dose of Pomalidomide, and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do not take 2 doses at the same time

If you take too much Pomalidomide or overdose, call your healthcare provider or poison control center right away

Want to Know More?

- For more information about Pomalidomide and/or the i-SECURE program:
  - Speak with your doctor
  - Call Biologix on +961-9-222050 extension 314 or 348 or Salehiya at: Ph. Mohammed Waqas-Pharmacovigilance Representative - Salehiya Trading Establishment - E-Mail : m.waqas@salehiya.com - PO Box 991, Riyadh 11421- - Kingdom of Saudi Arabia - Tel #+966 1 1464 6955 Ext 362 Fax #+966 1 1463 4362 - Mobile #+966 591211197

أي-سيكيور i-SECURE

كتيّب خّاص بّالمريض حّول عّلاج Pomalidomide بومالیدومايد

Pomalidomide

مقدمة لبرنامج i-SECURE

أوّلاً، يرتئي طبيبك وصف علاج Pomalidomide لك.

يرتبط هذا العلاج ارتباطًا هيكليًا باللثاليدومايد، الذي يعرف بأنه يسبّب تشوّهات خلقيّة شديدة تهدّد الحياة. لذلك من المتوقع أن يكون ال Pomalidomide ضارًا للطفل الذي لم يولد بعد. وبما أنّه قد سبّب عيوبًا خلقية عند الحيوانات، من الممكن أن يحدث تأثيرًا مماثلاً لدى البشر.

فلتجنّب تعريض حياة الجنين للخطر، لا يتمّ توفير ال Pomalidomide إلا في اطار برنامج توزيع خاص يسمّى i-SECURE.

وقد صُمّم هذا البرنامج لضمان أنّ العلاج يوصف ويؤخذ دائمًا بالطريقة الموصى بها.

السّمات الرئيسة للبرنامج:

- لا يوصف ال Pomalidomide إلا من قبل الأطباء المسجّلين في برنامج i-SECURE
- لا يباع ال Pomalidomide إلا من قبل الصيادلة أو في الصيدليات المسجّلة في برنامج i-SECURE
- لا يحصل على ال Pomalidomide إلا المرضى الملتحقين رسميًا ببرنامج i-SECURE

للالتحاق بهذا البرنامج، على المرضى أن يوقّعوا على "نموذج استئناف علاج Pomalidomide" ويوافقوا على تطبيق جميع متطلبات برنامج i-SECURE تطبيقًا كاملاً.

من المهمّ أن نتذكر أنّ:

ال Pomalidomide قد يسبّب تشوّهات خلقيّة أو قد يؤدّي إلى وفاة الأطفال الذين لم يولدوا بعد.

المحتويات

صفحة

متطلبات i-SECURE للنساء القادرات على الحمل

تشمل ما يلي:

يجب تصنيف النساء اللواتي لا ينطبق عليهنّ التعريف أدناه "غير القادرات على الإنجاب" على أنّهنّ قادرات على الإنجاب (FCBP).

فالنساء غير القادرات على الإنجاب هنّ:

١. النساء البالغات من العمر خمسين سنة أو أكثر واللواتي انقطع الطمث عندهنّ بشكل طبيعي منذ عامين أو أكثر
• لا يستبعد انقطاع الطمث، الذي يحدث من جرّاء علاج السرطان، القدرة على الإنجاب
٢. النساء اللواتي اختبرن فشل المبيض المبكر وقد أكّد الطبيب النسائي على ذلك
٣. النساء اللواتي لم يبدأ الطمث عندهنّ بعد
٤. النساء اللواتي خضعن لاستئصال الرحم أو المبيض والبوق الرحمي ثنائي الجانب
٥. النساء اللواتي يحملن التركيب الوراثي XY أو يعانين من متلازمة تيرنر أو من غياب الرحم عندهنّ.

هام: احرصي على عدم الحمل في خلال:

• الأسابيع الأربعة قبل بدء علاج Pomalidomide
• خضوعك لعلاج Pomalidomide
• أي انقطاع في علاج Pomalidomide
• مدّة أربعة أسابيع بعد انتهاء علاج Pomalidomide الخاص بك

قبل بدء العلاج:

١. يجب أن توقّعي على "نموذج استئناف علاج Pomalidomide" موافقةً على عدم الحمل في خلال خضوعك لعلاج Pomalidomide ومطبّقةً بذلك كافّة متطلبات برنامج i-SECURE.
٢. يجب أن تستخدمي وسيلتين فاعلتين لمنع الحمل في الوقت عينه قبل أربعة أسابيع من بدء العلاج. يمكنك مراجعة الأمثلة التالية عن بعض الوسائل الفعّالة لمنع الحمل:

o وسائل بغاية الفعالية

- وضع جهاز اللولب داخل الرحم (IUD)
- وسيلة هرمونية (زرع الهرمونات، وجهاز داخل الرحم يفرز الليفونورجيستريل (IUS)، وحقن لوضع خلات الميدروكسي بروجستيرون، والبروجستيرون المثبط للإباضة - على شكل حبوب فقط مثل الديزوجيسترل)
- ربط البوق الرحمي
- قطع القناة الدافقة عند الشريك

- وسائل عازلة فعّالة
  - الواقي الذكري
  - الحجاب الحاجز
  - غطاء عنق الرحم

يجب أن تتضمّن وسائل منع الحمل: ما لا يقلّ عن وسيلة واحدة بغاية الفعالية ووسيلة إضافية عازلة فعّالة تستخدمان في الوقت نفسه.

٣. يجب أن تقومي باختبار الحمل تحت إشراف طبي خلال زيارة طبيبك عند وصفه Pomalidomide لك، أو في خلال سبعة أيام من تأمين الصيدلي للدواء وذلك بعد قيامك باستخدام وسائل فعّالة لمنع الحمل لمدة أربعة أسابيع على الأقل. يجب أن يؤكّد الاختبار أنك لست حاملاً عند بدء علاج Pomalidomide
٤. يجب أن توافقي على عدم الإرضاع أو التبرّع بالدم
٥. يجب أن توافقي على عدم مشاركة أحد بحبوب Pomalidomide الخاصة بك
٦. يجب أن توافقي على إعادة حبوب Pomalidomide غير المستعملة إلى الصيدلي

خلال فترة العلاج والإخلال في تناول الجرعات:

١. يجب أن تستمرّي باستخدام وسيلتين فاعلتين لمنع الحمل في الوقت عينه أثناء العلاج، وخلال أي إخلال في علاج Pomalidomide
٢. يجب عليك أيضًا الخضوع بانتظام لاختبارات الحمل تحت إشراف طبّي كلّ أربعة أسابيع خلال فترة العلاج
٣. يجب ألا ترضعي أو تتبرّعي بالدم
٤. لا تعطي أحدًا من حبوب Pomalidomide الخاصة بك

ملاحظة: في حال عدم ظهور الدورة الشهرية عندك، أو في حال واجهت أي خلل في الطمث، أو إذا شككت أنك حامل أو إذا قمت بممارسة علاقة جنسية من دون استخدام وسيلة فعّالة لمنع الحمل:

- توقّفي فورًا عن علاج Pomalidomide
- أخبري طبيبك بذلك
- قومي باختبار الحمل

لمدة أربعة أسابيع بعد العلاج:

١. يجب أن تستمرّي باستخدام وسيلتين فاعلتين لمنع الحمل في الوقت عينه.
٢. يجب ألا ترضعي أو تتبرّعي بالدم.
٣. لا تعطي أحدًا من حبوب Pomalidomide الخاصة بك
٤. أعيدي حبوب Pomalidomide غير المستعملة إلى الصيدلي
٥. يجب أن تخضعي لاختبار الحمل تحت إشراف طبي لمدّة أربعة أسابيع بعد التوقف عن علاج Pomalidomide

ملاحظة: في حال عدم ظهور الدورة الشهرية عندك، أو في حال واجهت أي خلل في الطمث، أو حملت أو إذا قمت بممارسة علاقة جنسية من دون استخدام وسيلة فعّالة لمنع الحمل:

- أخبري طبيبك بذلك
- قومي باختبار الحمل

متطلبات i-SECURE للنساء غير القادرات على الحمل

تشمل ما يلي:

- النساء البالغات من العمر خمسين سنة أو أكثر واللواتي انقطع الطمث عندهنّ بشكل طبيعي منذ عامين أو أكثر
  - لا يستبعد انقطاع الطمث، الذي يحدث من جرّاء علاج السرطان، القدرة على الإنجاب
- النساء اللواتي اختبرن فشل المبيض المبكر وقد أكّد الطبيب النسائي على ذلك.
- النساء اللواتي خضعن لاستئصال الرحم أو المبيض والبوق الرحمي ثنائي الجانب
- النساء اللواتي يحملن التركيب الوراثي XY أو يعانين من متلازمة تيرنر أو من غياب الرحم عندهنّ.

Pomalidomide

قبل بدء العلاج:

١. يجب أن توقّعي على "نموذج استئناف علاج Pomalidomide" مشيرةً إلى أنّك غير حامل وغير قادرة على ذلك ومستعدّة لتطبيق كافّة متطلبات برنامج i-SECURE
٢. يجب أن توافقي على عدم التبرّع بالدم.
٣. يجب أن توافقي على عدم إعطاء أحد من حبوب Pomalidomide الخاصة بك
٤. يجب أن توافقي على إعادة حبوب Pomalidomide غير المستعملة إلى الصيدلي

خلال فترة العلاج والإخلال في تناول الجرعات:

١. لا تتبرّعي بالدم أبدًا.
٢. لا تعطي أحدًا من حبوب Pomalidomide الخاصة بك

لمدة أربعة أسابيع بعد العلاج:

١. لا تتبرّعي بالدم أبدًا.
٢. يجب أن تعيدي حبوب Pomalidomide غير المستعملة إلى الصيدلي

متطلبات i-SECURE للرجال

قبل بدء العلاج:

١. يتواجد ال Pomalidomide في السائل المنوي. يجب أن توقّع على "نموذج استئناف علاج Pomalidomide" موافقًا على استخدام الواقي الذكري في كل مرة تقوم فيها بعلاقة جنسية مع امرأة إمّا حامل أو ممكن أن تصبح حاملاً (حتى لو كنت قد قمت بقطع القناة الدافقة عندك) وغير مستخدمة لوسيلة بغاية الفعالية لمنع الحمل وتوافق كذلك على تطبيق كافّة متطلبات برنامج i-SECURE بما فيها الأمور التالية:

- يجب أن توافق على عدم التبرّع بالدم أو بالسائل المنوي.
- يجب أن توافق على عدم إعطاء أحد من حبوب Pomalidomide الخاصة بك
- يجب أن توافق على إعادة حبوب Pomalidomide غير المستعملة إلى الصيدلي

خلال فترة العلاج والإخلال في تناول الجرعات:

١. يجب أن تستخدم الواقي الذكري في كل مرة تقوم فيها بعلاقة جنسية مع امرأة إمّا حامل أو ممكن أن تصبح حاملاً (حتى لو كنت قد قمت بقطع القناة الدافقة عندك) وغير مستخدمة لوسيلة بغاية الفعالية لمنع الحمل
٢. يجب أن تخبر طبيبك إذا قمت بعلاقة جنسية مع امرأة من دون أن تستخدم الواقي الذكري أو إذا كنت تعتقد لأي سبب من الأسباب أن شريكتك قد تكون حاملاً
٣. يجب ألا تتبرّع بالدم أو بالسائل المنوي
٤. لا تعط أحدًا من حبوب Pomalidomide الخاصة بك

لمدة أربعة أسابيع بعد العلاج:

١. يجب أن تستمرّ باستخدام الواقي الذكري في كل مرة تقوم فيها بعلاقة جنسية مع امرأة إمّا حامل أو ممكن أن تصبح حاملاً (حتى لو كنت قد قمت بقطع القناة الدافقة عندك) وغير مستخدمة لوسيلة بغاية الفعالية لمنع الحمل
٢. يجب أن تخبر طبيبك إذا قمت بعلاقة جنسية مع امرأة من دون أن تستخدم الواقي الذكري أو إذا كنت تعتقد لأي سبب من الأسباب أن شريكتك قد تكون حاملاً
٣. يجب ألا تتبرّع بالدم أو بالسائل المنوي
٤. لا تعط أحدًا من حبوب Pomalidomide الخاصة بك
٥. أعد حبوب Pomalidomide غير المستعملة إلى الصيدلي

تحذيرات خاصة وتنبيهات

انخفاض عدد خلايا الدم البيضاء (نقص العدلات) والصفائح الدموية (نقص الصفيحات).

يسبّب ال Pomalidomide انخفاض عدد خلايا الدم البيضاء والصفائح الدموية لدى معظم المرضى. وقد تحتاج إلى نقل الدم أو إلى تناول بعض الأدوية إذا انخفض عدد خلايا الدم عندك بشكل كبير. يجب مراقبة عدد خلايا الدم الكامل في بداية العلاج، وأسبوعيًا لمدّة الأسابيع الثمانية الأولى وشهريًا بعد ذلك. يمكن أن تكون بحاجة لتعديل جرعة الدواء.

احتمال أكبر لحدوث جلطات الدم في الأوردة والرئتين.

اتّصل بطبيبك أو اطلب الحصول على المساعدة الطبية على الفور إذا ظهرت عندك أي من هذه العلامات أو الأعراض التالية:

أ. ضيق في التنفس
ب. آلام في الصدر
ج. تورّم في الذراع أو الساق

الآثار الجانبية المحتملة لل Pomalidomide

قد يسبّب Pomalidomide آثارًا جانبية خطيرة.
ردود فعل جلدية خطيرة. يمكن أن تحدث ردود فعل جلدية خطيرة نتيجة تلقّي علاج Pomalidomide
اتّصل بطبيبك على الفور إذا حصل عندك أي ردود فعل جلدية خلال تلقّي علاج Pomalidomide.

متلازمة تحلل الورم. يمكن أن تحدث مضاعفات في الأيض أثناء علاج مرض السرطان، وأحيانًا حتى من دون علاج. وتحدث هذه المضاعفات نتيجة موت الخلايا السرطانية ويمكن أن تشمل ما يلي: تغييرات في كيمياء الدم، ارتفاع نسبة البوتاسيوم والفوسفور وحمض اليوريك، وانخفاض معدل الكالسيوم مما يؤدي بالتالي إلى تغيّرات في وظائف الكلى، ودقّات القلب، والنوبات، ويؤدّي في بعض الأحيان إلى الموت.

من الآثار الجانبية الأكثر شيوعًا لل Pomalidomide في الجلد هي:

الإسهال
الغثيان
الإمساك
الطفح جلدي
التعب
الألم في العظام

وهذه ليست الآثار الجانبية كلّها المحتمل أن تظهر نتيجة علاج Pomalidomide. أخبر طبيبك عن أي آثار جانبية تزعجك أو لا تزول بسرعة.

كيف يجب أن تأخذ ال Pomalidomide؟

تناول ال Pomalidomide تمامًا كما وصف لك واتّبع جميع متطلّبات برنامج i-SECURE.

لا ينبغي أن يؤخذ ال Pomalidomide مع الطعام. (يجب أن يؤخذ قبل ساعتين على الأقل من وجبة الطعام أو بعدها بساعتين).

لا تفتح حبوب ال Pomalidomide أو تمسكها في يدك أكثر من اللازم.

إذا لمست حبّة مكسورة من ال Pomalidomide أو من الدواء الموجود في الحبّة، اغسل هذه المنطقة من جسمك بالصابون والماء.

إذا فوّتت جرعة من ال Pomalidomide، وذلك في أقل من 12 ساعة من الموعد المحدّد، تناول الحبة حالما تتذكر. إذا مرّ أكثر من 12 ساعة، تخطى الجرعة الفائتة. لا تأخذ جرعتين في الوقت نفسه.

إذا أخذت الكثير من ال Pomalidomide أو جرعة زائدة منه، اتصل فورًا بطبيبك أو بمركز علاج التّسمّم.

هل ترغب في معرفة المزيد من المعلومات؟

• لمزيد من المعلومات حول ال Pomalidomide و / أو برنامج i-SECURE:

- تحدث مع طبيبك
- اتصل ب Biologix على الرقم التالي: 222050-9-961+ واطلب 314 أو 348

اتصل بالمركز الوطني للتيقظ والسلامة الدوائية (NPC)
- الفاكس: 7662-205-11-966+
اتصل بالمركز على الرقم التالي: 2038222-11-966+ واطلب
2317-2356-2353-2354-2334-2340
- الرقم المجاني: 8002490000
- البريد الالكتروني: npc.drug@sfda.gov.sa
- الموقع الالكتروني: www.sfda.gov.sa/npc

i-SECURE
Pomalidomide Patient Brochure

Introducing i-SECURE

Your Doctor intends to prescribe Pomalidomide for you.

Pomalidomide is structurally related to thalidomide, which is known to cause severe life-threatening birth defects, therefore pomalidomide is expected to be harmful to the unborn child. Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans.

To avoid fetal exposure, Pomalidomide is available only under a special distribution program called i-SECURE.

The i-SECURE program is designed to ensure that Pomalidomide therapy is always prescribed and taken in the recommended way.

Key features of the program:

- Only physicians registered with i-SECURE can prescribe Pomalidomide
- Only pharmacists/pharmacies registered with i-SECURE can dispense Pomalidomide
- Only patients who have been formally enrolled in the i-SECURE program can receive Pomalidomide

To enroll, patients must sign a “Pomalidomide Treatment Initiation Form” and agree to fully comply with all requirements of the i-SECURE program.

IMPORTANT TO REMEMBER:

Pomalidomide may cause birth defects or death to unborn babies.

Content

Special i-SECURE Requirements for Females who are Able to Become Pregnant

Include:

Females who do not meet the below definition of Female NOT of childbearing potential should be classified as Females of childbearing potential (FCBP).

Females NOT of childbearing potential are:

1. Females ≥ 50 years old and naturally amenorrhoeic for ≥ 2 years
   - Amenorrhoea following cancer therapy does not rule out childbearing potential
2. Females that have premature ovarian failure confirmed by a gynecologist
3. Females that have not begun menstruation
4. Females with bilateral salpingo-oophorectomy or hysterectomy
5. Females with XY genotype, Turner's syndrome or uterine agenesis

Important: do NOT become pregnant:

- During the four weeks before starting Pomalidomide treatment
- While taking Pomalidomide
- During any interruption in Pomalidomide treatment
- During the four-week period following the conclusion of your Pomalidomide treatment

Before starting treatment:

1. You must sign a "Pomalidomide Treatment Initiation Form", agreeing not to become pregnant while taking Pomalidomide and following all requirements within i-SECURE
2. You must use two reliable methods of birth control (contraception) at the same time 4 weeks before starting Pomalidomide treatment. Refer below for examples of effective methods of contraception:
   - Highly effective methods
     - Intra Uterine Device (IUD)
     - Hormonal (hormonal implants, levonorgestrel-releasing intrauterine system (IUS), medroxyprogesterone acetate depot injections, ovulation inhibitory progesterone-only pills e.g. desogestrel)
     - Tubal ligation
     - Partner's vasectomy

- Effective barrier methods
  - Male condom
  - Diaphragm
  - Cervical cap

Contraceptive methods must include: At least 1 highly effective method AND 1 additional effective barrier method used at the same time.

3. You must have a medically supervised pregnancy test done during your consultation with the doctor, when Pomalidomide is prescribed, or in the 7 days prior to the dispensing by the pharmacist once you had been using effective contraception for at least 4 weeks. The test should ensure that you are not pregnant when you start treatment with Pomalidomide
4. You must agree to not breastfeed or donate blood
5. You must agree to never share your Pomalidomide capsules
6. You must agree to return unused Pomalidomide capsules to your pharmacist

During treatment and dose interruptions:

1. You must continue to use two reliable methods of birth control (contraception) at the same time during treatment and during any interruption in Pomalidomide treatment
2. You must also undergo regular medically supervised pregnancy tests every four weeks during treatment
3. You must not breastfeed or donate blood
4. Never share your Pomalidomide capsules

Note: If you miss a period, experience any abnormality in menstrual bleeding, suspect you are pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Stop Pomalidomide immediately
- Tell your doctor
- Have a pregnancy test

Pomalidomide

For four weeks after treatment:

1. You must continue to use two reliable methods of birth control (contraception) at the same time
2. You must not breastfeed or donate blood
3. Never share your Pomalidomide capsules
4. Return unused Pomalidomide capsules to your pharmacist
5. You must undergo a medically supervised pregnancy test 4 weeks after discontinuation of Pomalidomide therapy

Note: If you miss a period, experience any abnormality in menstrual bleeding, become pregnant or have sexual intercourse without using an effective means of birth control (contraception):

- Tell your doctor
- Have a pregnancy test

i-SECURE Requirements for Females who are NOT Able to Become Pregnant

Include:

- Females ≥ 50 years old and naturally amenorrheic for ≥ 2 years
  - Amenorrhea following cancer therapy does not rule out childbearing potential
- Females that have premature ovarian failure confirmed by a gynecologist
- Females with bilateral salpingo-oophorectomy or hysterectomy
- Females with XY genotype, Turner's syndrome or uterine agenesis

Pomalidomide

Before starting treatment:

1. You must sign a "Pomalidomide Treatment Initiation Form", indicating that you are not pregnant and do not have the ability to have children and will follow all requirements within i-SECURE
2. You must agree to not donate blood
3. You must agree to never share your Pomalidomide capsules
4. You must agree to return unused Pomalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1. You must not donate blood
2. Never share your Pomalidomide capsules

For four weeks after treatment:

1. You must not donate blood
2. Return unused Pomalidomide capsules to your pharmacist

i-SECURE Requirements for Male Patients

Before starting treatment:

1. Pomalidomide is present in semen. You must sign a "Pomalidomide Treatment Initiation Form", agreeing to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy) not using highly effective method of contraception and will follow all requirements within i-SECURE including the following:
   - You must agree to not donate blood, sperm or semen
   - You must agree to never share your Pomalidomide capsules
   - You must agree to return unused Pomalidomide capsules to your pharmacist

During treatment and during dose interruptions:

1 You must use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy) not using highly effective methods
2. You must tell your doctor if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your part ner may be pregnant
3. You must not donate blood, sperm or semen
4. Never share your Pomlidomide capsules

For four weeks after treatment:

1. You must continue to use a condom EVERY TIME you have sexual intercourse with a woman who either is or can become pregnant (even if you have had a successful vasectomy) not using highly effective methods
2. You must tell your doctor if you have sexual intercourse with a woman without using a condom, or if you think for any reason that your partner may be pregnant
3. You must not donate blood, sperm or semen
4. Never share your Pomlidomide capsules
5. Return unused Pomlidomide capsules to your pharmacist

Special Warnings and Precautions

Low white blood cells (neutropenia) and low platelets (thrombocytopenia).

Pomlidomide causes low white blood cells and low platelets in most patients. You may need a blood transfusion or certain medicines if your blood counts drop too low. Complete blood counts should be monitored at baseline, weekly for the first 8 weeks and monthly thereafter. A dose modification may be required.

Pomalidomide

A higher chance for blood clots in your veins and lungs.

Call your healthcare provider or get medical help right away if you get any of these signs or symptoms:

a. shortness of breath
b.chest pain
c. arm or leg swelling

Possible side effects of Pomalidomide

Pomlidomide may cause serious side effects.
Serious skin reactions. Serious skin reactions can happen with Pomlidomide
Call your healthcare provider right away if you have any skin reaction while taking Pomlidomide.

Tumor lysis syndrome. Metabolic complications that can occur during treatment of cancer and sometimes even without treatment. These complications are caused by the breakdown products of dying cancer cells and may include the following: changes to blood chemistry, high potassium, phosphorus, uric acid, and low calcium consequently leading to changes in kidney function, heart beat, seizures, and sometimes death.

Common side effects of skin Pomalidomide are:

Diarrhea
Nausea
Constipation
Rash
Tiredeness
Bone pain

These are not all the possible side effects of Pomalidomide. Tell your healthcare provider about any side effect that bothers you or that does not go away

Pomalidomide

How should you take Pomalidomide?

Take Pomalidomide exactly as prescribed and follow all the instructions of the i-SECURE program.

Pomalidomide should not be taken with food.(at least 2 hours before or 2 hours after a meal)

Do not open the Pomalidomide capsules or handle them any more than needed. If you touch a broken Pomalidomide capsule or the medicine in the capsule, wash the area of your body with soap and water

If you miss a dose of Pomalidomide, and it has been less than 12 hours since your regular time, take it as soon as you remember. If it has been more than 12 hours, just skip your missed dose. Do not take 2 doses at the same time

If you take too much Pomalidomide or overdose, call your healthcare provider or poison control center right away

Want to Know More?

- For more information about Pomalidomide and/or the i-SECURE program:
  - Speak with your doctor
  - Call Biologix on +961-9-222050 extension 314 or 348

Contact The National Pharmacovigilance and Drug Safety Centre (NPC)
-Fax: +966-11-205-7662
-Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
-Toll free phone: 8002490000
-E-mail: npc.drug@sfda.gov.sa
-Website: www.sfda.gov.sa/npc

i-SECURE
Pomalidomide

Adverse Event Report

Date Received by Biologix	Local Tracking N°	Page 1 of 3

1. Patient Details

Initials	Sex	Date of Birth
	Female ☐ Male ☐ Unk ☐	
Weight (kg)	Height (cm)	Race .....
Pregnant ?	No ☐ Yes* ☐ NA ☐ Unk ☐	
* Please give details in sections 8 or 11.		

2. Reporter Details : (Complete reporter details required for HCP, if Patient reporter just choose patient in the occupation section and state the country)

Name (For HCP) or Initials (for patient)	Occupation : .....
Address :	
Country :	Fax :
Phone 1 :	Email :
Phone 2 :	

3. Relevant Medical History : (Include primary diagnosis and preexisting medical conditions)

.....

4. Adverse Event Terms : *Relationship – only for HCP reports

"AS REPORTED TERM"					
Date Started	Date Stopped	Outcome	Relationship*	Prior History?	Serious?
"AS REPORTED TERM"					
Date Started	Date Stopped	Outcome	Relationship*	Prior History?	Serious?
"AS REPORTED TERM"					
Date Started	Date Stopped	Outcome	Relationship*	Prior History?	Serious?
"AS REPORTED TERM"					
Date Started	Date Stopped	Outcome	Relationship*	Prior History?	Serious?
"AS REPORTED TERM"					
Date Started	Date Stopped	Outcome	Relationship*	Prior History?	Serious?
"AS REPORTED TERM"					
Date Started	Date Stopped	Outcome	Relationship*	Prior History?	Serious?

5. Suspect Product (Include all cycles. Please record details of any dose reductions or increases)

Drug Name :	Vial Size :	Lot N°(s) :	Indication for Use :

Start Date	Stop Date	Dose	Units	Route	Frequency	Additional Comments

6. Action Taken on Suspect Product : (Please tick the appropriate boxes and record the dates if applicable and available)

☐ Unk

☐ None ☐ Dose Reduced ☐ Dose Increased ☐ Temporarily Withdrawn ☐ Permanently Withdrawn ☐ Discontinued (NOS)*

Dates :	Drug Reintroduced ☐ Yes ☐ N o
Date of last dose prior to discontinuation	Date :

**(NOS) = not otherwise specified*

Date Received by Biologix	Local Tracking N°	Page 2 of 3

7. Serious Criteria : (Please tick all appropriate boxes)

1. Fatal ☐	2. Persistant/Significant Disability ☐	3. Hospitalisation ☐	4. Medically Significant ☐	5. Congenital Abnormality ☐

1a. Date of Death :	3a. (Initial or Prolonged)
1b. Cause of Death :	3b. Admission Date :
	3c. Discharge Date :

8. Describe Event(s) :	Give a chronological summary of signs and symptoms. Please provide diagnosis, treatment, outcome, and autopsy details, if appropriate.
Initial report date :	.....
Follow-up 1 report date :	.....
Follow-up 2 report date :	.....
Follow-up 3 report date :	.....

9. Concomitant Medications :

Drug Name	Route	Dosage Units & Freq.		Start Date	Stop Date	Suspect Yes or No		Indication
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	

Date Received by Biologix	Local Tracking N°	Page 3 of 3

10. Corrective Treatments (given for the event)

Drug Name	Route	Dosage Units & Freq.		Start Date	Stop Date	Suspect Yes or No		Indication
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	
						☐	☐	

11. Relevant Diagnostic Tests : (Please provide the name, date, results and normal values for all diagnostic tests performed)

Name	Date	Results	

Comments on tests :	

Name of Recorder	Signature	Date

i-SECURE
Pomalidomide

Pregnancy Capture Form

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with Pomalidomide. Please send immediately to Biologix and/or Celgene.
As part of Biologix risk management plan (i-SECURE), it is essential to report all pregnancies for adequate follow up. Biologix/Celgene will therefore be in contact with you for further information in due course and would value your cooperation to ensure we are able to obtain all relevant information regarding foetal exposure to Pomalidomide. To report a pregnancy please contact:

1.Pharmacovigilance

Salehiya
Ph. Mohammed Waqas
Pharmacovigilance Representative - Salehiya Trading Establishment
E-Mail : m.waqas@salehiya.com - PO Box 991, Riyadh 11421
Kingdom of Saudi Arabia
Tel #+966 1 1464 6955 Ext 362 - Fax #+966 1 1463 4362
Mobile #+966 591211197

Biologix
Tel : 222050 9 961+
Fax : 222141 9 961+
Email : Pharmacovigilance@blgx.net

2. Drug Safety Europe, Celgene

Tel : 8476 723 32 41+
Fax : 8409 729 32 41+
Email : drugsafetyeurope@celgene.com

Reporter Information			
Reporter Name:		Occupation:	
Address:		City, Country:	
Phone No.: Fax No.:		Email address:	
Female Patient Information			
ID:	Age:	Date of Birth:	
Female Partner of Male Patient			
ID:	Age:	Date of Birth:	
Patient Treatment Information: Pomalidomide Capsule			
Batch No.:	Expiry Date:	Dose:	Frequency:
Start Date:		Stop Date:	
Indication for Use:			

Follow-up of the Pregnancy	Yes	No
Has the patient already been referred to an Obstetrician/Gynecologist		
If yes, please specify his/her name and contact details		
Reason for Failure of Pregnancy Prevention Program	Yes	No
Was patient erroneously considered not to be of childbearing potential		
If yes, state reason for considering not to be of childbearing potential		
a. Age 50 years and naturally amenorrhoeic for ≥ 2 years • Amenorrhoea following cancer therapy does not rule out childbearing potential		
b. Premature ovarian failure confirmed by a specialist gynecologist		
c. Previous bilateral salpingo-oophorectomy, or hysterectomy		
d. XY genotype, Turner syndrome, uterine agenesis		
Indicate from the list below which contraception was used	Yes	No
a. Implant		
b. Levonorgestrel-releasing intrauterine system (IUS)		
c. Medroxyprogesterone acetate depot		
d. Tubal sterilization (specify below)		
I. Tubal ligation		
II. Tubal diathermy		
III. Tubal clips		
e. Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses		
f. Ovulation inhibitory progesterone-only pills (i.e., desogestrel)		
g. Other progesterone-only pills		
h. Combined oral contraceptive pill		
i. Other intra-uterine devices		
j. Condoms		
k. Cervical cap		
l. Sponge		
m. Withdrawal		
n. Other		
o. None		
Indicate from the list below the reason for contraceptive failure	Yes	No
Missed oral contraception		
Other medication or intercurrent illness interacting with oral contraception		
Identified mishap with barrier method		
Unknown		
Had the patient committed to complete and continuous abstinence		
Was Pomalidomide started despite patient already being pregnant		
Did patient receive educational material on the potential risk of teratogenicity		
Did patient receive instructions on need to avoid pregnancy		

Prenatal Information	
Date of last menstrual period:	Estimated delivery date:

Pregnancy test	Reference range	Date
Urine qualitative		
Serum quantitative		

Past Obstetric History

Year of pregnancy	Outcome					
	Spontaneous abortion	Therapeutic abortion	Live birth	Still birth	Gestational age	Type of delivery

Birth Defects	Yes	No	Unknown
Was there any birth defect from any pregnancy			
Is there any family history of any congenital abnormality			

If yes to either of these questions, please provide details below

.....

.....

Maternal Past Medical History

Condition	Dates		Treatment	Outcome
	From	To		

Maternal Current Medical Conditions		
Condition	Date	Treatment

Maternal Social History	Yes	No
Alcohol		
If yes, amount/units per day:		
Tobacco		
If yes, amount per day:		
IV or recreational drug use		
If yes, provide details:		

Maternal Medication During Pregnancy and in 4 Weeks Before Pregnancy
(including herbal, alternative and over-the-counter medicines and dietary supplements)

Medication/Treatment	Start date	Stop date/ Continuing	Indication

Name of Person Completing this Form	Signature	Date

i-SECURE
Pomalidomide

Pregnancy Capture Form

Please complete this form to report a pregnancy in a patient (or in a female partner of a male patient) treated with Pomalidomide. Please send immediately to Biologix and/or Celgene.
As part of Biologix risk management plan (i-SECURE), it is essential to report all pregnancies for adequate follow up. Biologix/Celgene will therefore be in contact with you for further information in due course and would value your cooperation to ensure we are able to obtain all relevant information regarding foetal exposure to Pomalidomide. To report a pregnancy please contact:

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Salehiya
Ph. Mohammed Waqas
Pharmacovigilance Representative - Salehiya Trading Establishment
E-Mail : m.waqas@salehiya.com - PO Box 991, Riyadh 11421
Kingdom of Saudi Arabia - Tel #+966 1 1464 6955 Ext 362 -
Fax #+966 1 1463 4362 - Mobile #+966 591211197

Biologix
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2. Drug Safety Europe, Celgene

Tel : 8476 723 32 41+
Fax : 8409 729 32 41+
Email : drugsafetyeurope@celgene.com

Reporter Information			
Reporter Name:		Occupation:	
Address:		City, Country:	
Phone No.: Fax No.:		Email address:	
Female Patient Information			
ID:	Age:	Date of Birth:	
Female Partner of Male Patient			
ID:	Age:	Date of Birth:	
Patient Treatment Information: Pomalidomide Capsule			
Batch No.:	Expiry Date:	Dose:	Frequency:
Start Date:		Stop Date:	
Indication for Use:			

Follow-up of the Pregnancy	Yes	No
Has the patient already been referred to an Obstetrician/Gynecologist		
If yes, please specify his/her name and contact details		
Reason for Failure of Pregnancy Prevention Program	Yes	No
Was patient erroneously considered not to be of childbearing potential		
If yes, state reason for considering not to be of childbearing potential		
a. Age 50 years and naturally amenorrhoeic for ≥ 2 years • Amenorrhoea following cancer therapy does not rule out childbearing potential		
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Year of pregnancy	Outcome					
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Condition	Dates		Treatment	Outcome
	From	To		

Maternal Current Medical Conditions		
Condition	Date	Treatment

Maternal Social History	Yes	No
Alcohol		
If yes, amount/units per day:		
Tobacco		
If yes, amount per day:		
IV or recreational drug use		
If yes, provide details:		

Maternal Medication During Pregnancy and in 4 Weeks Before Pregnancy
(including herbal, alternative and over-the-counter medicines and dietary supplements)

Medication/Treatment	Start date	Stop date/ Continuing	Indication

Name of Person Completing this Form	Signature	Date