Pomalidomide SPC® (Pomalidomide)
Pregnancy Prevention Programme

Information for Healthcare Professionals
Prescribing or Dispensing Pomalidomide

*This document has been reviewed and approved by The **Saudi Food and Drug Authority (SFDA).***
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Mail to: Riyadh Gallery Mall, Building A2,
Office 305-A, Riyadh, Saudi Arabia
Phone: 920001432, ext. 107
Fax: 00966 11 4668195
Email: Pharmacovigilance@SudairPharma.com
www.SudairPharma.com

This brochure contains the information needed for prescribing and dispensing pomalidomide, including information about the Pregnancy Prevention Programme (PPP). Please also refer to the Summary of Product Characteristics (SmPC), which can be found on the Saudi Drug Information System (SDI) website: https://sdi.sfda.gov.sa/, for further information.

Pomalidomide SPC® Pregnancy Prevention Programme:

If **Pomalidomide SPC®** is taken during pregnancy it can cause severe birth defects or death to an unborn baby. This Programme is designed to make sure that unborn babies are not exposed to **Pomalidomide SPC®**. It will provide you with information about how to follow the programme and explain your responsibilities.

Other side effects of **Pomalidomide SPC®**:

A full list of all side effects, further information and recommended precautions can be found in the **Pomalidomide SPC®** SmPC.

Important information about the safe disposal of unwanted capsules and restrictions on donating blood during treatment is also included in this brochure.

This brochure will help you understand these problems and make sure you know what to do before prescribing and dispensing **Pomalidomide SPC®**.

For your patient's health and safety, please read this brochure carefully. You must ensure that your patients fully understand what you have told them about Pomalidomide SPC® and that they have provided written confirmation on the Treatment Initiation Form, before starting treatment.

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Contents

1.0 Introduction

1.1 Licensed Indications

Pomalidomide in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.

For this indication, the recommended starting dose of pomalidomide is 4 mg orally once daily on Days 1 to 14 of repeated -21day cycles. Pomalidomide is administered in combination with bortezomib and dexamethasone. The recommended starting dose of bortezomib is 1.3 mg/m2 intravenous or subcutaneous once daily, on the days shown in Table 1 in Section 4.2 of the SmPC. The recommended dose of dexamethasone is 20 mg orally once daily, on the days shown in Table 1 in Section 4.2 of the SmPC. Treatment with pomalidomide combined with bortezomib and dexamethasone should be given until disease progression or until unacceptable toxicity occurs.

For patients >75 years of age, the starting dose of dexamethasone is 10 mg once daily on Days 11 ,9 ,8 ,5 ,4 ,2 ,1 and 12 of each -21day cycle for Cycles 1 to 8 and 10 mg once daily on Days 8 ,2 ,1 and 9 of each -21day cycle for Cycles 9 and onwards. No dose adjustment is required for pomalidomide. For bortezomib, refer to the current SmPC for additional information.

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

For this indication, the recommended starting dose of pomalidomide is 4 mg orally once daily on Days 1 to 21 of repeated -28day cycles (-28/21days). The recommended dose of dexamethasone is 40 mg orally once daily on Days 15 ,8 ,1 and 22 of each -28day treatment cycle. Treatment with pomalidomide combined with dexamethasone should be given until disease progression or until unacceptable toxicity occurs.

For patients >75 years of age, the starting dose of dexamethasone is 20 mg once daily on Days 15 ,8 ,1 and 22 of each -28day treatment cycle. No dose adjustment is required for pomalidomide.

For full details, please refer to the SmPC, which can be found on the emc website www.medicines.org.uk.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

1.2 Summary of the Pomalidomide SPC® Pregnancy Prevention Programme

This brochure contains the information needed for the prescribing and dispensing of pomalidomide including information about the Pregnancy Prevention Programme.

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 of pomalidomide in humans is expected. Pomalidomide is therefore contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme are met (please refer to sections 4.4 and 4.6 of the SmPC for further details).

- All men and all women of childbearing potential should undergo, at treatment initiation, counselling of the need to avoid pregnancy (this must be documented via a Treatment Initiation Form and checklists for counselling are provided)
- Patients should be capable of complying with the requirements of safe use and handling of pomalidomide
- Patients must be provided with a copy of the Patient Brochure.

In order to obtain pomalidomide, it is a requirement of the Pregnancy Prevention Programme that all healthcare professionals ensure that they have read and understood the information provided in this pack before prescribing or dispensing pomalidomide for any patient.

- Prescribers must complete the appropriate Treatment Initiation Form with every patient before the first prescription is issued.
- Pharmacies must register with Sudair Pharma to be able to order and dispense pomalidomide. To do this, the pharmacist use the paper Pharmacy Registration Form.
- Every prescription for pomalidomide must be accompanied by a Prescription Authorisation Form, which can be completed by completing of the paper Prescription Authorisation Form.
- The paper Pharmacy Registration Form and Prescription Authorisation Form are in subsequent sections of this pack.

All patients should be given a Patient Brochure to take home – these materials remind patients of the key educational information and risks of treatment, and can be found in the Information for Patients section of this pack.

For women of childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks of treatment and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

1.3 Overview of the Healthcare Professional's Information Pack

All of the **Pomalidomide SPC®** Pregnancy Prevention Programme materials are contained within this pack and additional copies can be obtained by using the contact details displayed on the front of this brochure.

You must ensure that your patients fully understand what you have told them about pomalidomide before starting treatment.

This book contains key information for healthcare professionals and contains the following:

- educational information
- therapy management advice to avoid foetal exposure to pomalidomide
- a distribution control system

- Safety advice of relevance to all patients
- Process for follow-up of effectiveness of the measures described in this pack
- Process for reporting adverse events and pregnancy in patients treated with pomalidomide.

The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in the attached Algorithm.

1.4 Teratogenicity: Potential or Actual Foetal Exposure to Pomalidomide

Pomalidomide must never be used by women who are able to become pregnant unless they follow the **Pomalidomide SPC®** Pregnancy Prevention Programme described in this pack (Section 2.0).

Since pomalidomide may be present in the semen of male patients, all male and female patients must both follow effective contraceptive measures.

If a female patient or female partner of a male patient misses, or is suspected to have missed her period, or has any abnormality in menstrual bleeding, or suspects she is pregnant, then:

- Pomalidomide must be discontinued immediately
- The woman must have a pregnancy test
- If the pregnancy test is positive, the woman should be referred to a physician experienced in teratology for further evaluation and counselling.

Any positive pregnancy test or suspected foetal exposure to pomalidomide must be reported immediately to the In this instance you must:

- Stop treatment immediately
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation
- Notify Sudair Pharma immediately by contacting the (Email: **Pharmacovigilance@SudairPharma.com**). Please also complete the Pregnancy Reporting Form included in this pack and send it to the will wish to follow-up with you on the progress of all pregnancies
- Report the event to the Saudi Food and Drug Authority SFDA via the following email: **npc@sfda.gov.sa** website: **https://ade.sfda.gov.sa/**

1.5 Safety Advice Relevant to all Patients

In addition to information about the Pregnancy Prevention Programme, this brochure contains important advice for Healthcare Professionals about how to minimise the risk of adverse events during treatment

2.0 Therapeutic Management Advice to Avoid Foetal Exposure

2.1 Women of Non-Childbearing Potential

Women in the following groups are considered not to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice:

- Age ≥50 years and naturally amenorrhoeic for ≥1 year. Please note amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential
- Confirmed premature ovarian failure confirmed by a specialist gynaecologist
- Previous bilateral salpingo-oophorectomy, or hysterectomy
- XY genotype, Turner syndrome, uterine agenesis.

Women of childbearing potential are all other women who are menstruating or perimenopausal, even those who abstain from sexual intercourse. Prescribers are advised to refer their patient for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

2.2 Women of Childbearing Potential

Women of childbearing potential must never take pomalidomide if:

- Pregnant
- They are able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Programme are met.

In view of the teratogenic risk of pomalidomide, foetal exposure should be avoided.

Women of childbearing potential must understand the need to avoid pregnancy, and these patients must be adequately informed regarding the use of effective contraceptive measures every time a prescription is issued.

Women of childbearing potential (even if they have amenorrhoea) must use at least one effective method of contraception for at least 4 weeks before therapy, during therapy, and until at least 4 weeks after pomalidomide therapy finished, and even in case of dose interruption. This must be followed unless the patient commits to absolute and continuous abstinence confirmed to her prescriber on a monthly basis.

If your patient is not established on effective contraception, she must be referred to

for contraceptive advice in order that a contraception an appropriately trained health care professional can be initiated.

The following can be considered to be examples of suitable methods of contraception:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel).

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking pomalidomide and dexamethasone, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

Implants and levonorgestrel-releasing intrauterine systems are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered particularly in patients with neutropenia.

Insertion of copper-releasing intrauterine devices is not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may com-

promise patients with severe neutropenia or severe thrombocytopenia.

Your patient should be advised that if a pregnancy does occur whilst she is receiving pomalidomide, she must stop treatment immediately and immediately inform her physician.

If your patient needs to change or stop her method of contraception during her pomalidomide therapy, she must understand the need to discuss this first with:

- The physician prescribing her method of contraception
- The physician prescribing her pomalidomide.

If a woman of childbearing potential has sexual contact without using an effective contraception method while taking pomalidomide or believes for any reason that she may be pregnant, she must stop treatment and consult her prescriber immediately.

Pregnancy Testing

For women of childbearing potential a pregnancy test must be performed prior to issuing a prescription. This may be embarrassing for some patients and may need to be handled sensitively. A pregnancy test is required even if the patient has not had heterosexual intercourse since her last pregnancy test.

Women of childbearing potential (even if they have amenorrhoea) must have a medically supervised negative pregnancy test prior to issuing a prescription (with a minimum sensitivity of 25 mIU/ml) once she has been established on contraception for at least 4 weeks, at least every 4 weeks during therapy (this includes dose interruptions) and at least 4 weeks after the end of therapy (unless confirmed tubal sterilisation). This includes those women of childbearing potential who confirm absolute and continued abstinence.

Patients who are being prescribed the appropriate contraceptive method by their physician, should inform their physician about pomalidomide treatment. Patients should be advised to inform you if a change or stop of method of contraception is needed.

A pregnancy test must be performed immediately if a patient misses her period, if there is any abnormality in menstrual bleeding, if she has heterosexual intercourse without using a contraceptive method, or if she suspects she is pregnant.

If a female patient has a positive pregnancy test, then:

- Stop treatment immediately
- Refer the patient to a physician specialised or experienced in dealing with teratology for advice and evaluation
- Notify Sudair Pharma via the following email: **pharmacoviglance@sudairpharma.com**
- Report the outcome to the Saudi Food and Drug Authority SFDA via the following email: **npc@sfda.gov.sa**

2.3 Men

In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided. Therefore your male patients must be counselled at treatment initiation on the risks and benefits of pomalidomide therapy including the risk of birth defects, other side effects and important precautions associated with pomalidomide therapy. Inform your patient which are the effective contraceptive methods that his female partner can use.

Pomalidomide is present in human semen. As a precaution, and taking into account special populations with potentially prolonged elimination time such as renal impairment, all male patients taking pomalidomide, including those who have had a vasectomy as seminal fluid may still contain pomalidomide in the absence of spermatozoa, should use condoms throughout treatment duration, during dose interruption and for at least 7 days after cessation of treatment if their partner is pregnant or of childbearing potential and has no contraception.

Patients should be instructed that if their partner does become pregnant whilst he is taking pomalidomide or within 7 days after he has stopped taking pomalidomide, he should inform his prescriber immediately. The partner should inform their physician immediately. It is recommended that she be referred to a physician specialised in teratology for evaluation and advice. Report the event to the Saudi Food and Drug Authority SFDA via the following email: **npc@sfda.gov.sa**

2.4 Advice for all Patients

Your patient must be informed not to donate blood during or within 7 days after stopping treatment. If your patient discontinues therapy, they must return any unused pomalidomide to the pharmacy.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

They must also understand that their pomalidomide is only for them, and it:

- Must not be shared with anyone else, even if they have similar symptoms
- Must be stored away safely so no one else could take the capsules by accident
- Must be kept out of reach and sight of children.

3.0 Healthcare Professional Obligations

Healthcare Professionals have specific obligations that must be followed when prescribing or dispensing pomalidomide, which are:

Prescriber: You must ensure that

- Your patient is fully educated on the risks of pomalidomide
- you complete the appropriate "Treatment initiation form" with your patient before the first prescription is isseued
- You provide the patient with a Patient Brochure and a copy of the 'Treatment Initiation Form'
- If relevant, your patient is using the appropriate method of contraception
- Female patients of childbearing potential undergo a pregnancy test, which must be negative, before every prescription that you issue
- You complete a 'Prescription Authorisation Form' with every prescription
  - this includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription
- You prescribe pomalidomide in accordance with the measures described in this brochure and the SmPC

Pharmacist: You must ensure that

- Your pharmacy is registered with the **Pomalidomide SPC®** Pregnancy Prevention Programme. Registration will be valid for 2 years
- Pomalidomide is only dispensed if the prescription is accompanied by a Prescription Authorisation Form. This includes instances where pomalidomide is prescribed to in-patients or if a prescription has to be dispensed in two parts due to the unavailability of sufficient stock to fulfil the prescription
- You check and validate the 'Prescription Authorisation Form' prior to dispensing pomalidomide
- You dispense pomalidomide in accordance with the measures described in this brochure
- You send a copy of the Prescription Authorisation Form immediately to Sudair Pharma
- You remind patients of key education messages each time pomalidomide is dispensed.

3.1 Information for Prescribers

3.1.1 Patient and Healthcare Professional Education

As the prescriber, you play a central role in ensuring that pomalidomide is used safely and correctly. Most importantly, you will be helping to ensure that your patients understand the risks involved in taking pomalidomide and that they are aware of their responsibilities in preventing foetal exposure to the drug. In addition, you may need to help your patients understand the processes involved in the **Pomalidomide SPC®** Pregnancy Prevention Programme. This will help to prevent any delays in your patients receiving their treatment.

If you refer your patient to a fertility expert (e.g. obstetrician or gynaecologist) for further contraceptive advice or pregnancy testing counselling, it is your responsibility to ensure that the fertility expert is aware of the **Pomalidomide SPC®** Pregnancy Prevention Programme.

3.1.2 Patient Counselling and Education

Because of the different levels of risk, you will need to communicate different information to men, women and children. You must ensure that your patient understands the information before they complete their section of the Treatment Initiation Form.

Please make use of the Patient Brochure and to help explain the relevant information. Copies of the Brochure are contained in your 'Healthcare Professional's Information Pack', and your patient should take these materials home to read in their own time or with a relative. Further copies can be obtained by using the contact details displayed on the front of this brochure.

3.1.3 Prescribing Pomalidomide

3.1.3.1 Maximum Prescription Lengths

- For women of childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 4 weeks of treatment according to the approved indications dosing regimens (posology; see Introduction) and continuation of treatment requires a new prescription. Dispensing will not occur unless a negative pregnancy test was performed within 3 days prior to the prescription
- For all other patients, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

3.1.3.2 Initial Prescription

- Before issuing the initial prescription, you must:
- Counsel the patient on the safe use of pomalidomide in accordance with the measures described in this brochure and the SmPC.
- Obtain their written confirmation (using the correct Treatment Initiation Form) that they have received and understood this information, and provide the patient with a copy.

- Provide the patient with a Patient Brochure.
- 'Prescription Authorisation Form' must be provided to the patient with each pomalidomide prescription, and this will contain:
  - Patient initials, date of birth and diagnosis.
  - Prescriber name, signature and date.
  - Patient risk category (women of childbearing potential, women of non-childbearing potential, or male).
  - Confirmation that they have received counselling on the safe use of pomalidomide
  - For women of childbearing potential, the pregnancy test date and result.

The patient must present their 'Prescription Authorisation Form' to the pharmacy along with their prescription, and the pharmacy will check this form prior to dispensing pomalidomide.

Once the Prescription Authorisation Form has been checked for completeness, a copy of the Prescription Authorisation Form must be sent to Sudair Pharma.

3.1.3.3 Repeat of subsequent prescriptions

The patient must return to the prescriber for every repeat prescription of pomalidomide.

3.2 Information for Pharmacists

As a pharmacist, you play an important role in ensuring that pomalidomide is used safely and correctly. Pomalidomide will only be supplied to pharmacies that have completed an '**Pomalidomide SPC®** Pregnancy Prevention Programme, Pharmacy Registration Form' and returned this form to Sudair Pharma

3.2.1 Dispensing pomalidomide

In order to be registered, the Chief Pharmacist or appointed deputy of the institution wishing to dispense must agree to implement and audit the use of a Prescription Authorisation Form.

Along with each pomalidomide prescription, prescribers must complete a Prescription Authorisation Form and instruct the patient to provide this to their pharmacy. You must only dispense pomalidomide if the prescriber has annotated this form correctly. When completing the Prescription Authorisation Form via the paper Prescription Authorisation Form, it asks the

prescriber to confirm:

- The patient's diagnosis
- Whether the patient is male or female

- If female, the patient's childbearing potential
- If of childbearing potential that adequate contraception is in place and the date of the last negative pregnancy test, which must be within the 3 days prior to the date of prescription
- If male, counselling regarding the use of condoms has taken place
- That a Treatment Initiation Form has been completed by the patient
- That the prescriber has read and understood the contents of this Healthcare Professional Information Pack.

When completing the Prescription Authorisation Form, it asks the pharmacist to confirm;

- That the Prescription Authorisation Form has been completed in full by the prescriber
- The dispensing for women of childbearing potential is taking place within 7 days of the prescription date
- That the pharmacist has read and understood the contents of this Healthcare Professional Information Pack.

For women of childbearing potential, prescriptions for pomalidomide should be limited to a maximum duration of 4 weeks and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day. Dispensing of pomalidomide should occur within a maximum of 7 days of the prescription and the date of the last negative pregnancy test must be within the 3 days prior to the date of the prescription.

For males and women of non childbearing potential, prescriptions of pomalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription.

3.2.2 Dispensing Advice

- For each prescription, dispense a maximum of a 4week supply for women of childbearing potential or a 12week supply for all other patients
- Please educate all pharmacists within your pharmacy about the dispensing procedures for pomalidomide
- Instruct patients to return any unused pomalidomide to the pharmacy. Pharmacies must accept any unused pomalidomide returned by patients for destruction, and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

4.0 Follow-up Assessment of the Effectiveness of the Programme

The terms of the **Pomalidomide SPC®** Marketing Authorisation require Sudair Pharma to assess the effectiveness of the Pregnancy Prevention Programme in order to ensure that all reasonable steps are being taken to reduce the risk of pregnancy exposure in patients treated with pomalidomide.

Sudair Pharma is therefore obliged to perform audits at regular intervals and to report appropriately anonymous and aggregated results to the SFDA .

Sudair Pharma to obliged to provide the anonymised reports on the data received from the Prescription Authorisation Forms to the regulatory agencies. The reports are used to assess the effectiveness of risk minimisation activities and Sudair Pharma will not be able to comply if pharmacies do not provide ALL their Prescription Authorisation Forms to Sudair Pharma.

5.0 Safety Advice Relevant to all Parties

The following section contains advice to Healthcare Professionals about how to minimise the risk of thrombocytopenia and cardiac failure associated with the use of pomalidomide. Please refer also to SmPC (Sections 4.2 Posology and method of administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Undesirable effects) for complete information on all the risks associated with pomalidomide.

In general, most adverse reactions occurred more frequently during the first 2 to 3 months of treatment. Please note that the posology, adverse event profile and recommendations outlined herein, particularly in respect of neutropenia and thrombocytopenia, relate to the use of pomalidomide within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication.

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to treatment.

5.1 Risk of thrombocytopenia and cardiac failure with pomalidomide

5.1.1 Thrombocytopenia

Thrombocytopenia is one of the major dose-limiting toxicities of treatment with pomalidomide.

It is therefore encouraged to monitor complete blood counts - including platelet count - weekly for the first 8 weeks and monthly thereafter.

A dose modification or interruption may be required. Patients may require use of blood product support and /or growth factors.

Thrombocytopenia can be managed with dose modifications and/or interruptions. Recommended dose modifications during treatment and restart of treatment with pomalidomide are outlined in the following table:

Dose Modification or Interruption Instructions

Toxicity	Dose Modification
Thrombocytopenia • Platelet Count <25 x 10^9/L • Platelet Count return to 50 x 10^9/L	Interrupt pomalidomide treatment, follow CBC weekly. Resume pomalidomide treatment at one dose lower than previous dose.
• For each subsequent drop <25 x 10^9/L • Platelet count return to 50 x 10^9/L	Interrupt pomalidomide treatment Resume pomalidomide treatment at one dose level lower than the previous dose.

CBC – Complete Blood Count

To initiate a new cycle of pomalidomide, the the platelet count must be 50 x 10^9/L.

Thrombocytopenia occurred in 27.0% of patients who received POM + LD-Dex, and 26.8% of patients who received HD-Dex. Thrombocytopenia was Grade 3 or 4 in 20.7% of patients who received POM + LD-Dex and in 24.2% who received HD-Dex. In POM + LD-Dex treated patients, thrombocytopenia was infrequently serious in 1.7% of patients, led to dose reduction in 6.3% of patients, to dose interruption in 8% of patients and to treatment discontinuation in 0.7% of patients (see Section 4.8 of the SmPC)

5.1.2 Cardiac Failure

Cardiac events, including congestive cardiac failure, pulmonary oedema and atrial fibrillation (see Section_4.8 of the SmPC), have been reported, mainly in patients with pre-existing cardiac disease or cardiac risk factors. Appropriate caution should be exercised when considering the treatment of such patients with pomalidomide, including periodic monitoring for signs or symptoms of cardiac events (see Section 4.4 of the SmPC).

5.2 Safety and Off-Label Use

Please note that the posology, adverse event profile and recommendations outlined above, relate to the use of pomalidomide within its licensed indication. Pomalidomide must always be used according to the Pregnancy Prevention Programme described in this pack

– these precautions must be followed, irrespective of the treatment setting, including the indication for treatment. It is essential that the patient›s diagnosis is entered on the Prescription Authorisation Form - this will allow an assessment of the clinical usage of pomalidomide, which is important for ongoing monitoring of safety.

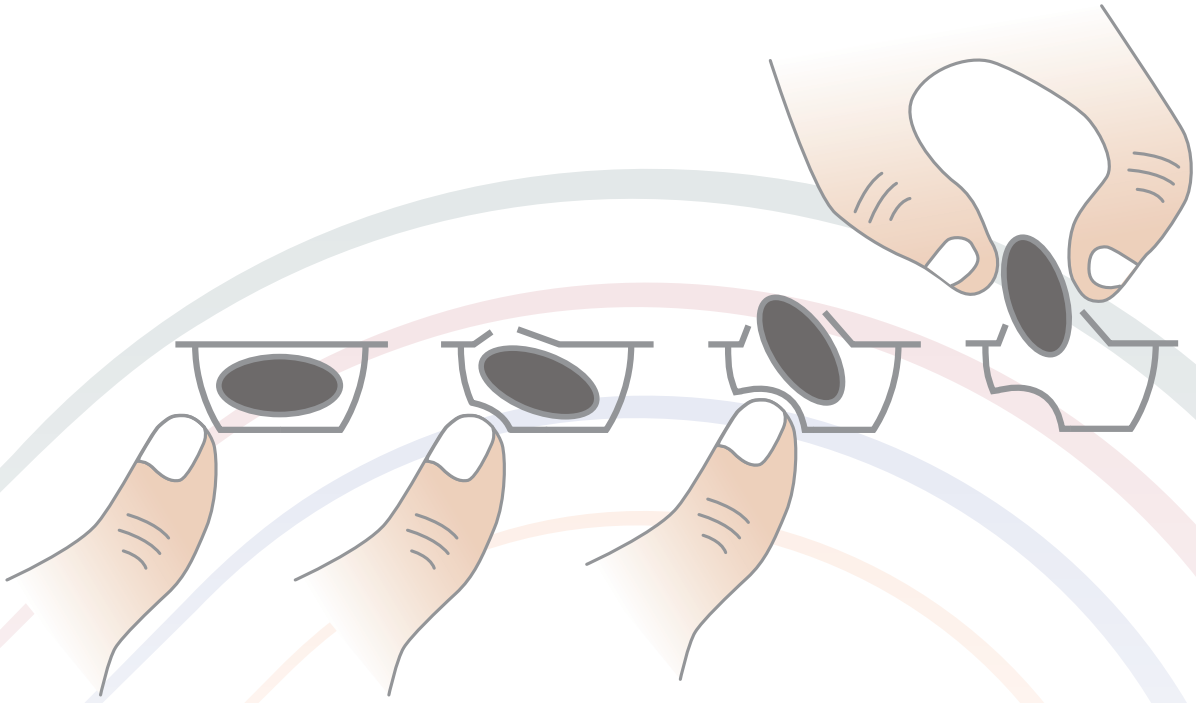
5.3 Points to Consider for Handling the Medicinal Product: For Healthcare Professionals and Caregivers

Keep the blisters with the capsules in the original pack.

Capsules can occasionally become damaged when pressing them out of the blister, especially when the pressure is put onto the middle of the capsule. Capsules should not be pressed out of the blister by putting pressure on the middle nor by putting pressure on both ends as this can result in deformation and breaking of the capsule.

It is recommended to press only on one site at the end of the capsule (see figure below) as therefore the pressure is located to one site only which reduces the risk of capsule deformation or breakage.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule. Refer overleaf for further guidance.



When handling the medicinal product use the following precautions to prevent potential exposure if you are a healthcare professional or caregiver

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
- Wear disposable gloves when handling product and/or packaging (i.e. blister or capsule)
- Use proper technique when removing gloves to prevent potential skin exposure (see overleaf)
- Place gloves in sealable plastic polyethylene bag and dispose according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves
- Patients should be advised never to give pomalidomide to another person.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure

• If outer carton is visibly damaged **– Do Not Open**

• If blister strips are damaged or leaking or capsules are noted to be damaged or leaking **– Close Outer Carton Immediately**

• Place the product inside a sealable plastic polyethylene bag

• Return unused pack to the pharmacist for safe disposal as soon as possible.

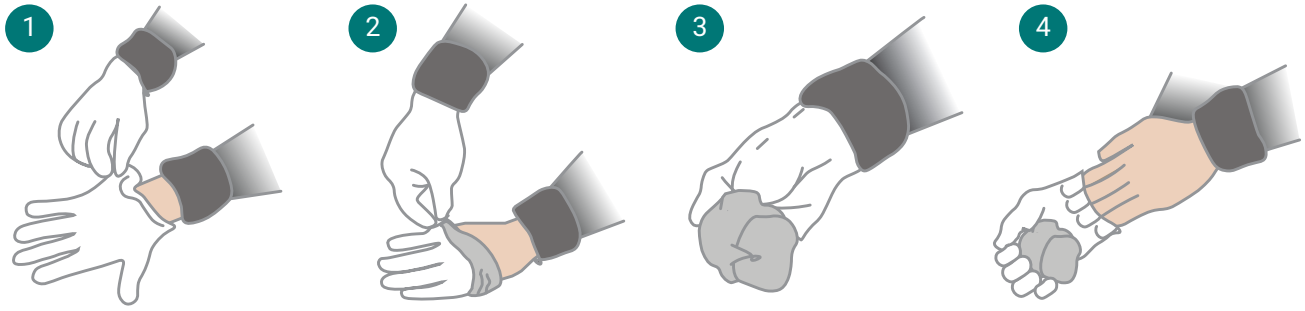
If product is released or spilled, take proper precautions to minimise exposure by using appropriate personal protection

- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder
- Wear disposable gloves to clean up the powder
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water and dry it
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag and dispose in accordance to local requirements for medicinal products
- Wash your hands thoroughly with soap and water after removing the gloves
- Please report to the Celgene Drug Safety Department (Tel: 9908 238 0808 or drugsafetyuk@celgene.com).

If the contents of the capsule are attached to the skin or mucous membranes

- If you touch the drug powder, please wash exposed area thoroughly with running water and soap
- If the powder gets in contact with your eye, if worn and if easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs please contact an ophthalmologist

Proper Technique for Removing Gloves



- Grasp outside edge near wrist (1)
- Peel away from hand, turning glove inside-out (2)
- Hold in opposite gloved hand (3)
- Slide ungloved finger under the wrist of the remaining glove, be careful not to touch the outside of the glove (4)
- Peel off from inside, creating a bag for both gloves
- Discard in appropriate container
- Wash your hands with soap and water thoroughly.

5.4 Blood Donation

All patients should not donate blood during treatment (including dose interruptions) and for at least 7 days after cessation of treatment with pomalidomide.

6.0 Reporting Adverse Events and Suspected Pregnancy

6.1 Requirements in the event of a suspected pregnancy

- Stop treatment immediately if the patient is a female
- Refer female patient to a physician specialised or experienced in teratology for evaluation and advice
- Notify Sudair Pharma of all suspected pregnancies in female patients or partners of male patients
  - Pharmacovigilance Department, Sudair Pharma Company E-mail: Pharmacovigilance@sudairpharma.com Tel: 92 000 1432 - Ext.: 107 Mobile: 0546030507 will wish to follow up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.
- Pregnancy reports should also be reported to the SFDA National Pharmacovigilance and Drug Safety Center at Saudi Food and Drug Authority SFDA E-mail: npc.drug@sfda.gov.sa Online: https://ade.sfda.gov.sa Toll free phone: 19999

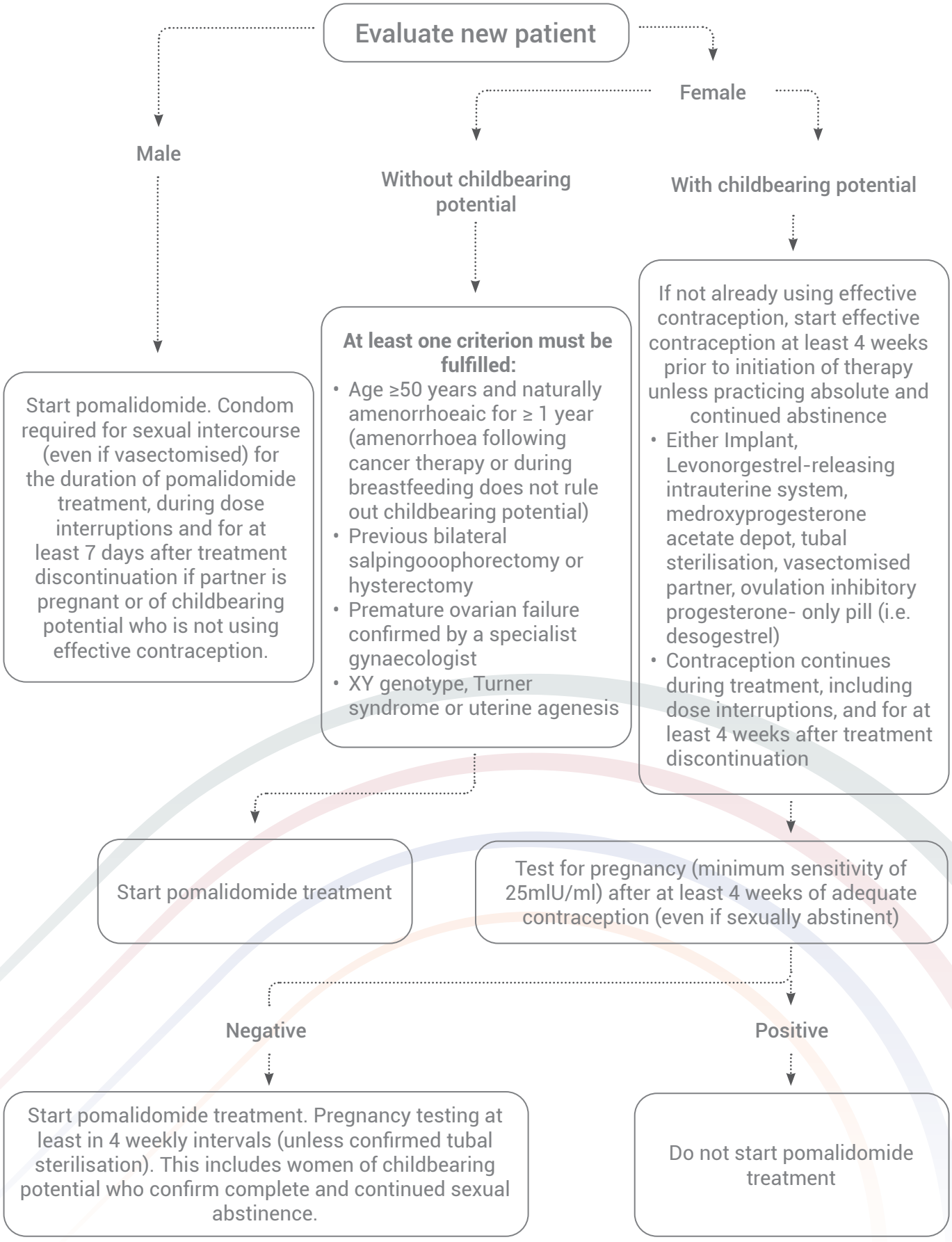
Treatment for a woman of childbearing potential cannot start until patient is established on at least one effective method of contraception for at least 4 weeks or commits to complete and continued abstinence and pregnancy teat is negative

6.2 Reporting of Adverse Reactions

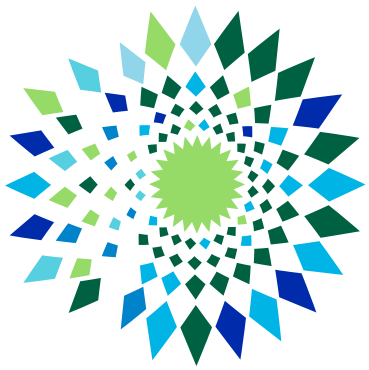
The safe use of pomalidomide is of paramount importance. As part of Celgene's ongoing safety monitoring, the company wishes to learn of adverse reactions that have occurred during the use of pomalidomide. Adverse Reaction report forms are included in this Healthcare Professional›s Information Pack.

Pharmacovigilance Department, Sudair Pharma Company
E-mail: Pharmacovigilance@sudairpharma.com
Tel: 92 000 1432 - Ext.: 107
Mobile: 0546030507
National Pharmacovigilance and Drug Safety Center at Saudi Food and Drug Authority SFDA
E-mail: npc.drug@sfda.gov.sa
Online: https://ade.sfda.gov.sa
Toll free phone: 19999

7.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm



Mail to: Riyadh Gallery Mall, Building A2,
Office 305-A, Riyadh, Saudi Arabia
Phone: 920001432, ext. 107
Fax: 00966 11 4668195
Email: Pharmacovigilance@SudairPharma.com
www.SudairPharma.com



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*This document has been reviewed and approved by The **Saudi Food and Drug Authority (SFDA).***
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