



i-SECURE

Patient Brochure for the Immunomodulatory agent Imnovid[®] (Pomalidomide)

This Educational material is part of the Marketing authorization and has been approved by the SFDA in August 2023

Patient Brochure for Immunomodulatory Agents

You have been prescribed an immunomodulatory agent. This type of treatment can cause birth defects. It is extremely important that you do not take them if you are pregnant, or planning to become pregnant. If you are able to become pregnant and are not using an effective contraceptive (birth control) method, do not use this treatment. This brochure is to help ensure safe use and handling of the immunomodulatory agent.

If used during pregnancy, the immunomodulatory agents, thalidomide and pomalidomide, can harm the developing fetus. Potential risks include loss of the fetus and birth defects. Please make sure that you have read and understood the following information prior to starting treatment with immunomodulatory agents. If you have any questions or concerns about your treatment, please reach out to your healthcare professional.

A. For all patients:

- You should never share your immunomodulatory agents with anyone else.
- You should store immunomodulatory agents safely so that no-one else can take the medicine by accident. Ensure that immunomodulatory agent is out of reach of children.
- You should not open, crush, or overly handle the capsules.
- You should always dispose of any unused capsules according to local regulations at the end of your treatment.
- For more information on safe handling of the immunomodulatory agent, please refer to the Product Handling Instructions for Immunomodulatory Agents.
- You should not donate blood during treatment, even during dose interruptions, or for at least 7 days after stopping treatment.
- If you experience any side effects while taking immunomodulatory agents, you should tell your healthcare professional.
- For additional information, please refer to the Package Leaflet.
- You must never take immunomodulatory agents if:
 1. You are pregnant, or
 2. You are able to become pregnant, even if you are not planning to, unless all of the conditions of the Pregnancy Prevention Program are met.

B. If you are a woman who is able to become pregnant:

1. You must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of your treatment, even during dose interruptions, and for at least 4 weeks after stopping treatment. Your healthcare professional will advise you on appropriate methods of contraception. Some types of contraception are not recommended during treatment with immunomodulatory agents. That's why it's essential that you discuss this with your healthcare

professional. The following methods are examples of effective contraception:

Implant, levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilization, sexual intercourse with a vasectomized male partner only (vasectomy must be confirmed by two negative semen analyses), and ovulation inhibitory progesterone-only pills (i.e. desogestrel)

OR

2. You agree and confirm every month that you will **NOT** engage in heterosexual intercourse.

AND

- You will have pregnancy tests under the supervision of your healthcare professional before treatment. These will be repeated at least every 4 weeks during treatment, even during dose interruptions, and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilization), even if you confirm absolute and continuous sexual abstinence from heterosexual intercourse on a monthly basis.
- You should start treatment with your immunomodulatory agent as soon as possible after a negative pregnancy test result and having received your medication.
- If you become pregnant while on immunomodulatory agents, you must stop treatment immediately and inform your healthcare professional immediately. They may recommend that you see a type of healthcare professional specializing in developmental abnormalities of the fetus.

C. If you are a male:

- You must use condoms even if you have had a vasectomy as seminal fluid may still contain the product in the absence of spermatozoa, throughout the duration of your treatment, even during dose interruptions, and for at least 7 days after stopping treatment if your partner is pregnant or can become pregnant and not using effective contraception.
- You must not donate semen or sperm during treatment, even during dose interruptions, and for at least 7 days after stopping treatment as immunomodulatory agents can pass into seminal fluid.
- You should inform your treating healthcare professional immediately if your partner becomes pregnant while you are taking or within 7 days after you have stopped taking immunomodulatory agents. Your partner should inform her healthcare professional immediately. It is recommended that she be referred to a healthcare professional specializing in abnormalities of the fetus for evaluation and advice.

For more information about the effects and side effects of your treatment, please refer to the Patient Information Leaflet.