Imnovid®▼
(pomalidomide)

Pregnancy Prevention Programme

Information for Patients taking Pomalidomide

UK
Version 8

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

You can help by reporting any side effects you may get. Report the suspected side effect using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

Risk Management contact details:
Tel: 0808 156 3059
Fax: 0808 156 3058
Email: rmpukire@bms.com

Medical Information Queries:
Email: medical.information@bms.com

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This brochure contains information about:

Preventing harm to unborn babies: If pomalidomide is taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby.

Imnovid Pregnancy Prevention Programme: This programme is designed to make sure that unborn babies are not exposed to pomalidomide. It will provide you with information about what to expect from your treatment, and explain the risks and your responsibilities.

Pomalidomide must never be used by a woman who is pregnant. In addition, it is important to know that pomalidomide passes into men's semen, and is expected to cause severe birth defects or death to an unborn baby. So if you are a male patient, there is a risk if you have unprotected sex with a woman who can become pregnant.

This brochure will help you understand what to do before, during and after taking pomalidomide.

This brochure will not give you information about multiple myeloma, you should ask your prescriber if you have any questions.

Warning: Severe life-threatening birth defects. If pomalidomide is taken during pregnancy, it can cause severe birth defects or death to an unborn baby.

Pomalidomide must never be used by women who are pregnant, as just one capsule can cause severe birth defects.

Pomalidomide must never be used by women who are able to become pregnant unless they follow the Imnovid Pregnancy Prevention Programme.

For complete information on all possible side effects please read the Package Leaflet that comes with your pomalidomide capsules.

This brochure also contains important information about the requirement to avoid blood donation during treatment, the safe handling of pomalidomide and the safe disposal of unused pomalidomide capsules.

For your own health and safety, please read the patient information leaflet and this brochure carefully. If you do not understand something, please ask your prescriber for further explanation.

Contents

Introduction

Imnovid is the trade name for pomalidomide and it is used to treat adults with a type of cancer called 'multiple myeloma'. Pomalidomide works in a number of different ways:

- by stopping the cancer cells developing.
- by stimulating the immune system to attack the cancer cells.
- by stopping the formation of blood vessels supplying the cancer cells.

Pomalidomide is either used with:

- two other medicines - called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have had at least one other treatment - including lenalidomide.

Or

- one other medicine - called 'dexamethasone' in people whose myeloma has become worse, despite having at least two other treatments - including lenalidomide and bortezomib.

Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. Therefore, if pomalidomide is taken during pregnancy, a teratogenic effect is expected.

Pomalidomide has been shown to produce birth defects in animals and it is expected to have a similar effect in humans. Therefore precautions must be taken to avoid exposure to pomalidomide in an unborn baby.

This brochure is part of the "Imnovid Pregnancy Prevention Programme", which is necessary because if pomalidomide is taken during pregnancy it can cause severe birth defects or death to an unborn baby.

This brochure contains important information about the Imnovid Pregnancy Prevention Programme. You must read the information carefully and before starting treatment you should:

- Understand the risks of pomalidomide treatment.
- Understand the guidelines for taking pomalidomide safely, including how to prevent pregnancy.
- Understand what to expect during your initial and follow-up consultations with your prescriber.
- Your prescriber will explain to you the risks of pomalidomide treatment and specific instructions that you must follow.
- Please make sure that you understand what your prescriber has told you before starting pomalidomide.

If you don't understand something, please ask your prescriber for further explanation.

Pomalidomide and Birth Defects

All medicines can cause unwanted effects or 'side effects'. An extremely important side effect of pomalidomide is that if taken during pregnancy, it can cause severe birth defects or death to an unborn baby. The birth defects include shortened arms or legs, malformed hands or feet, eye or ear defects, and internal organ problems. This means pomalidomide must never be taken by:

- Women who are pregnant.
- Women who could become pregnant, unless they follow the Imnovid Pregnancy Prevention Programme.

Pomalidomide and Other Possible Side Effects

Like all medicines, pomalidomide can cause side effects, although not everybody gets them. Some side effects are more common than others and some are more serious than others. Ask your prescriber or pharmacist if you would like more information, and refer to the Package Leaflet. Most side effects are temporary and can be easily prevented or treated. The most important thing is to be aware of what to expect and what to report to your prescriber. It is important that you talk to your prescriber if you have any side effects during pomalidomide treatment.

You can report suspected pregnancies and side effects online using the Yellow Card Scheme via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary);
- by emailing yellowcard@mhra.gov.uk;
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789;
- or by downloading and printing a form from the Yellow Card section of the MHRA website.

Side effects and suspected pregnancies should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com.

Before and during the treatment with pomalidomide you will have regular blood tests. This is because your medicine may cause a fall in the number of blood cells that help fight infection (white cells) and in the number of cells that help to stop bleeding (platelets).

Your prescriber should ask you to have a blood test:

- before treatment.
- every week for the first 8 weeks of treatment.
- at least every month after that for as long as you are taking pomalidomide.

As a result of these tests, your prescriber may change your dose of pomalidomide or stop your treatment. The prescriber may also change the dose or stop the medicine because of your general health.

Pregnancy Prevention Programme

- You should tell your prescriber if you are pregnant or think you may be pregnant or are planning to become pregnant, **as pomalidomide is expected to be harmful to an unborn child.**
- **Before starting treatment your prescriber will ask you to read and sign a Risk Awareness Form.**

What should you tell your prescriber before taking pomalidomide:

- If you are pregnant, if you think you may be pregnant or if you are planning to become pregnant, **as pomalidomide is expected to be harmful to an unborn child.**
- If you think you are able to become pregnant and need advice on effective contraception.
- If you are breastfeeding.
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing while taking related medicines called 'thalidomide' or 'lenalidomide'.
- If you have previously had an allergic (hypersensitive) reaction such as rash, itching, swelling, feeling dizzy or trouble breathing to any other ingredient in pomalidomide capsules. Ask your pharmacist for advice.
- If you have had a heart attack, have heart failure, have difficulty breathing, if you smoke, have high blood pressure or high cholesterol levels.
- If you have a history of thrombosis (blood clots).
- If you are taking or have recently taken any other medicines, including medicines bought without a prescription.

- If you have a high total amount of tumour throughout the body, including your bone marrow. This could lead to a condition where the tumours break down and cause unusual levels of chemicals in the blood which can lead to kidney failure. You may also experience an uneven heartbeat. This condition is called tumour lysis syndrome.
- If you have or have had neuropathy (nerve damage causing tingling or pain in your hands or feet).
- If you have or have ever had hepatitis B infection. Treatment with pomalidomide may cause the hepatitis B virus to become active again in patients who carry the virus, resulting in a recurrence of the infection. Your prescriber should check whether you have ever had hepatitis B infection.
- If you experience or have experienced in the past a combination of any of the following symptoms: rash on face or extended rash, red skin, high fever, flu-like symptoms, enlarged lymph nodes, signs of severe skin reaction called Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or drug hypersensitivity syndrome, Toxic Epidermal Necrolysis (TEN) or Stevens-Johnson Syndrome (SJS).

Childbearing Potential Assessment

Do not take Imnovid® if you are pregnant or think you may be pregnant or are planning to become pregnant – this is because **Imnovid® is expected to be harmful to an unborn child**. Unless you fall into one of the following categories, you must follow the contraceptive advice presented in this section:

- You are at least 50 years old and it has been at least one year since your last period (if your periods have stopped because of cancer therapy or during breastfeeding, then there is still a chance you could become pregnant).
- Your womb has been removed (hysterectomy).
- Your fallopian tubes and both ovaries have been removed (bi-lateral salpingo oophorectomy).
- You have premature ovarian failure, confirmed by a specialist gynaecologist.
- You have the XY genotype, Turner syndrome or uterine agenesis.

You may need an appointment and tests with a specialist in female medicine to confirm that you cannot become pregnant. Every woman who is able to become pregnant even if they are not planning to, must follow the precautions detailed in this section.

Contraception Methods for Women of Childbearing Potential

You must never take pomalidomide if:

- You are pregnant.
- You are a woman who is able to become pregnant, even if you are not planning to become pregnant.

Pomalidomide is expected to be harmful to the unborn child

- If you are able to become pregnant, you must follow all the necessary measures to prevent you becoming pregnant and ensuring you are not pregnant during treatment. Before starting the treatment, you should ask your prescriber if you are able to become pregnant, even if you think this is unlikely.
- If you are able to become pregnant and even if you agree and confirm every month that you will not engage in heterosexual activity, you will have pregnancy tests under the supervision of your prescriber before treatment. These will be repeated at least every 4 weeks during treatment, during dose interruption and at least 4 weeks after the treatment has finished (unless it is confirmed that you have had a tubal sterilisation).
- If you are able to become pregnant, unless you commit to absolute and continuous abstinence confirmed on a monthly basis, you must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the duration of your treatment (including dose interruptions), and for at least 4 weeks after stopping treatment. Your prescriber will advise you on appropriate methods of contraception as some types of contraception are not recommended with pomalidomide. It is essential therefore that you discuss this with your prescriber.
- If you suspect you are pregnant at any time whilst taking pomalidomide or in the 4 weeks after stopping treatment, you must stop pomalidomide immediately and immediately inform your prescriber. Your prescriber will refer you to a physician specialised or experienced in teratology for evaluation and advice.

- Inform the prescriber of your contraception that you are on pomalidomide.
- Inform your prescriber of pomalidomide if you have changed or stopped the method of contraception.
- Before starting pomalidomide treatment you should discuss with your prescriber whether or not there is any possibility that you could become pregnant. Some women who are not having regular periods or who are approaching the menopause may still be able to become pregnant.
- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for you **NOT** to become pregnant throughout the duration of your treatment with pomalidomide and for at least 4 weeks after stopping pomalidomide.
- You should start your pomalidomide treatment as soon as possible after having a negative pregnancy test result and having received pomalidomide.

Contraception to Prevent Pregnancy

If you are a woman who could become pregnant you must either:

- Use adequate contraception starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment

or

- Agree you will not engage in sexual activity with a male partner starting at least 4 weeks before pomalidomide treatment, during pomalidomide treatment, during any breaks in pomalidomide treatment and for at least 4 weeks after stopping pomalidomide treatment. You will be asked to confirm this every month.

Not all types of contraception are suitable during pomalidomide treatment. You and your partner should discuss with your prescriber suitable forms of contraception that you both find acceptable. If necessary, your health care professional can refer you to a specialist for advice on contraception.

Contraception Methods for Males

Pomalidomide is expected to be harmful to the unborn child

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you have been informed of the requirement for your partner **NOT** to become pregnant throughout the duration of your treatment with pomalidomide and for at least 7 days after you stop pomalidomide.
- Ask your prescriber to inform you of which are the effective contraceptive methods that your female partner can use.
- Pomalidomide passes into human semen. If your partner is pregnant or able to become pregnant, and she doesn't use effective contraception, you must use condoms throughout the duration of your treatment, during dose interruptions and at least 7 days after you stop pomalidomide even if you have had a vasectomy.
- If your partner does become pregnant whilst you are taking pomalidomide or within 7 days after you have stopped taking pomalidomide, you should inform your prescriber immediately and your partner should also consult her doctor immediately.
- You should not donate semen or sperm during treatment, during dose interruptions and for at least 7 days after stopping treatment.

Women of Non Childbearing Potential

Pomalidomide is expected to be harmful to the unborn child.

- In order to ensure that an unborn baby is not exposed to pomalidomide, your prescriber will complete a Risk Awareness Form documenting that you are not able to become pregnant.
- You should never share pomalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- For additional information, please refer to the Package Leaflet.

Pomalidomide Treatment

Before Starting Your Treatment

Your prescriber will talk to you about what to expect from your treatment, and explain the risks and your responsibilities. If there is anything you do not understand, please ask your prescriber to explain it further.

Before starting treatment your prescriber will ask you to read and sign a Risk Awareness Form, which confirms that while taking pomalidomide:

- You understand the risks of birth defects.
- You agree not to become pregnant.
- You understand the other important safety messages. Your prescriber will keep this form with your medical records and will also provide you with a copy.

Safety Information for all patients

- You must never take pomalidomide if you are allergic to pomalidomide or to any of the other ingredients contained in the capsule.
- You should never share pomalidomide with anyone else.
- You should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- You should not donate blood during treatment, during dose interruptions, or for at least 7 days after stopping treatment.
- If you experience any side effects whilst taking pomalidomide you should tell your prescriber or pharmacist.
- For additional information, please refer to the Package Leaflet.

Receiving Your Prescription

Your prescriber may provide you with a 'Prescription Authorisation Form (PAF)' that must be provided to the pharmacist, which confirms that all of the Imnovid Pregnancy Prevention Programme measures have been followed. Your pharmacist will ask to review this documentation prior to dispensing your pomalidomide. Alternatively, your prescriber may complete the PAF electronically, in which case the PAF will be sent directly to the pharmacist.

For women of childbearing potential your prescriber will write a prescription for no more than 4 weeks supply, provided you have had a valid negative pregnancy test within 3 days prior to your prescription date and you must have the medication dispensed within 7 days of the prescription date.

For women of non-childbearing potential and male patients your prescriber will write a prescription for no more than 12 weeks supply.

You will need to see your prescriber each time you need a repeat prescription.

How to Take your Medication

Your pharmacist can give you help and advice on taking your medicines. Some people find it helpful to mark on a calendar when they have taken their medicines each day or to set an alarm clock to remind them to take their medicines.

- Your prescriber will prescribe a dose of pomalidomide suited to you.
- Your prescriber may adjust your dose depending on the result of blood tests and any side-effects you may experience.
- Do not take more capsules than your prescriber has prescribed. If in doubt, ask your prescriber or pharmacist for advice.
- The capsules should not be opened, broken or chewed.
- Pomalidomide capsules should be swallowed whole, with a glass of water, and can be taken with or without food.
- Pomalidomide can be taken at any time of day but it should be taken at approximately the same time each day.

What to do if you have taken more than the prescribed dose of pomalidomide

If you accidentally take too many capsules, contact your prescriber immediately.

Taking other medicines

Please tell your prescriber or pharmacist if you are taking or have recently taken any other medicines, including medicines bought without a prescription. If you are seeing a different prescriber or other healthcare professional for treatment (your dentist for example) you should tell them that you are taking pomalidomide and dexamethasone.

How to store pomalidomide safely

- Keep your pomalidomide in a safe place out of the sight and reach of children.
- Keep your pomalidomide capsules in the original carton.
- Do not use after the expiry date stated on the blister and carton.

End of Treatment Requirements

After completing your pomalidomide treatment, it is important that:

- You return any unused pomalidomide capsules to your pharmacist.
- You do not donate blood for at least 7 days.

Additional advice for women of childbearing potential:

- Continue using your effective method of contraception for at least a further 4 weeks.
- Your prescriber will perform a final pregnancy test after at least 4 weeks, unless it is confirmed you have had a tubal sterilisation.

Additional advice for male patients:

- If you have been using an effective method of contraception, you must continue doing so for at least a further 7 days.
- If your female partner has been using an effective method of contraception, she must continue doing so for at least a further 4 weeks.
- Do not donate semen or sperm for at least 7 days.

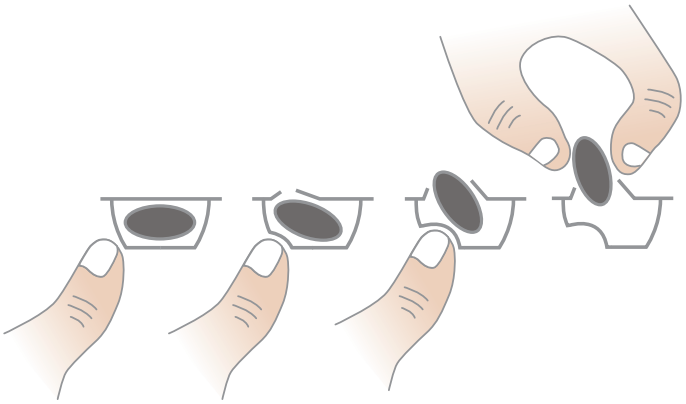
Points to Consider for Handling the Medicinal Product: For Patients, Family Members and Caregivers

Do not share the medicinal product with anyone else, even if they have similar symptoms. Store them safely so that no-one else can take them by accident and keep them out of the reach of children.

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. The pressure should be located at one site only, which reduces the risk of the capsule. deforming or breaking (see figure below).

Healthcare professionals, family members and caregivers should wear disposable gloves when handling the blister or capsule. Remove gloves carefully to prevent skin exposure. Place in a sealable plastic polyethylene bag. Dispose of any unused medication in accordance with local regulations. 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 Family Member and/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 the proper technique when removing gloves to prevent potential skin exposure (see below).
- Place gloves in a sealable plastic polyethylene bag and dispose them according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.
- Do not give pomalidomide to another person.

If a Drug Product Package Appears Visibly Damaged, Use the Following Extra Precautions to Prevent Exposure:

- If the 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:

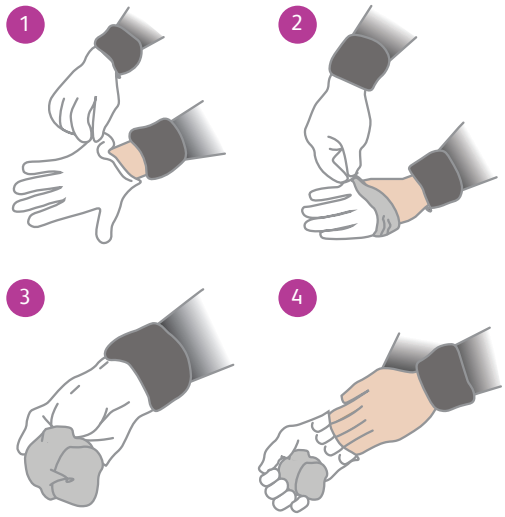
- If capsules are crushed or broken, dust containing drug substance may be released.
- Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water, then dry it.
- Place all contaminated materials including damp cloth or towel and the gloves into a sealable polyethylene plastic bag. Dispose of it according to local requirements for medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.
- Please report to the prescriber and/or pharmacist immediately.

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, being 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.



Personal Notes

Please use this space to write down any questions for your prescriber for discussion at your next appointment.

Checklist

Please use this check list to confirm that you have understood all of the important information regarding your pomalidomide treatment.

All Patients

- ☐ Yes, I have understood that I should never share pomalidomide with anyone else.
- ☐ Yes, I have understood that I should always return any unused capsules to the pharmacist for safe disposal as soon as possible.
- ☐ Yes, I have received and understood all the information on the risks of birth defects associated with taking pomalidomide.
- ☐ Yes, I have received and understood all the information on the risks of other side effects associated with taking pomalidomide.
- ☐ Yes, I have understood that I must not donate blood during treatment (including dose interruptions), and for at least 7 days after stopping treatment.
- ☐ Yes, I understand that I need to sign the Risk Awareness Form before starting treatment.

Male Patients

- ☐ Yes, I have understood the need to use condoms during treatment, during dose interruption and for at least 7 days after stopping pomalidomide, if I have a female partner who is pregnant or is able to get pregnant and not using effective contraception.
- ☐ Yes, I have understood I must not donate semen or sperm during treatment (including during dose interruptions) and for at least 7 days after stopping pomalidomide.

Female Patients who can become pregnant

- ☐ Yes, I will use one effective method of contraception for at least 4 weeks before starting pomalidomide, during therapy (even in the case of dose interruptions) and for at least 4 weeks after I have stopped pomalidomide treatment.
- ☐ Yes, I understand that I need to have a negative pregnancy test result before starting to take my treatment, and for at least every 4 weeks during treatment and at least 4 weeks after stopping treatment (except in the case of confirmed tubal sterilisation).

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