Pomalidomide Rowex
Pregnancy Prevention Programme and Information for Healthcare Professionals Prescribing or Dispensing Pomalidomide

Approved by the Malta Medicines Authority on the 13th January 2026.

REPORTING OF ADVERSE REACTIONS

Suspected adverse reactions and medication errors should be reported either to:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta
Website:
www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

OR

Marketing Authorisation Holder:
Rowex Limited
Tel: 0877941968
Email: adverse.event.ireland@sandoz.net

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1.0 Introduction

This guide contains the information needed for the prescribing and dispensing of pomalidomide, including information about the Pregnancy Prevention Programme (PPP) and important safety information. This guide will help you understand these precautions and make sure you know what to do before prescribing and dispensing pomalidomide.

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

To ensure your patients' health and safety, please read this guide carefully. You must ensure that your patients fully understand what you have told them about pomalidomide and that they have provided written confirmation on the Risk Awareness Form, before starting treatment

Pomalidomide Pregnancy Prevention Programme:

Pomalidomide is an immunomodulating medicinal product.

If pomalidomide is taken during pregnancy it is expected to 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. It will provide you with information about how to follow the programme and explain your responsibilities.

It is a requirement of the Pregnancy Prevention Programme that all healthcare professionals (HCPs) ensure that they have read and understood the Healthcare Professionals Information guide before prescribing or dispensing pomalidomide for any patient.

For full information regarding the requirements of the Pregnancy Prevention Programme, as well as safety information, side effects and recommended precautions please also refer to the relevant Summary of Product Characteristics (SmPC).

When pomalidomide is given in combination with other medicinal products, the corresponding SmPC must be consulted prior to initiation of treatment. Please refer to the relevant Summary of Product Characteristics (SmPC).

2.0 Pomalidomide Rowex Programme

Pomalidomide is structurally related to thalidomide. Thalidomide is 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). This programme is designed to make sure that unborn babies are not exposed to pomalidomide.

- It is a requirement of the Pregnancy Prevention Programme that all Healthcare Professionals ensure that they have read and understood this guide before prescribing or dispensing pomalidomide for any patient.
- You must ensure that your patient fully understands what you have told them about pomalidomide before starting the treatment. 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 Risk Awareness Form which is available for this purpose).
- 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 Guide, Risk Awareness Form and Patient Pocket Information Card. These materials remind patients of the key educational information regarding the requirements of the pregnancy prevention programme and some of the important risks of treatment outlined in the Healthcare Professional Information Guide

Hard copies of the pomalidomide Rowex Pregnancy Prevention Programme materials can be obtained by using the contact details displayed on the back of this guide. Electronic copies of the materials are also available for download from the Malta Medicines Authority website.

The following are core requirements of the pomalidomide Pregnancy Prevention Programme:

- A controlled distribution system
- All healthcare professionals dispensing or prescribing pomalidomide must read and understand the Pomalidomide Healthcare Professional’s Information Guide.

- Every prescription for pomalidomide must be accompanied by a Prescription Authorisation Form which must be completed by the prescriber and the pharmacist.

The description of the Pregnancy Prevention Programme and the categorisation of patients based on sex and childbearing potential is set out in this Healthcare Professional`s Information Guide, see section 9.0.

3.0 Safety Advice to Avoid Foetal Exposure

3.1 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 amenorrhoeaic for ≥ 1 year. Please note amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential
- 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 patients for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

3.2 Women of Childbearing Potential

Women of childbearing potential must never take pomalidomide if they are:

- Pregnant
- 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 expected teratogenic risk of pomalidomide, foetal exposure must be avoided.

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 **or**
- commit to absolute and continuous abstinence confirmed on a monthly basis

AND

- have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/mL) once she has been established on contraception for at least 4 weeks, at least in 4-weekly intervals 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 sexual abstinence.

There must be no more than 3 days between the dates of the last negative pregnancy test and the prescription. Best practice is for the pregnancy test, prescribing and dispensing to take place on the same day.

If not established on effective contraception, the patient must be referred to an appropriately trained healthcare professional for contraceptive advice in order that contraception 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).

Patients should be advised to inform the healthcare professional prescribing her contraception about the pomalidomide treatment.

Patients should be advised to inform you if a change or stop of method of contraception is needed.

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL THE PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

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 are generally not recommended due to the potential risks of infection at the time of insertion and menstrual blood loss which may compromise 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 prescriber.

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

- The prescriber prescribing her contraceptive method.
- The prescriber prescribing her pomalidomide.

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

Requirements in the event of a suspected pregnancy while on treatment with pomalidomide Rowex:

- **Stop treatment immediately**
- **Refer the patient to a physician specialised or experienced in dealing with teratology for evaluation and advice.**
- **Notify the relevant Marketing Authorisation Holder Risk Management (see section 10.0 for contact details) immediately of all such occurrences. Please also complete the Pregnancy Reporting Form for the relevant Marketing Authorisation Holder. The relevant Marketing Authorisation Holder will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.**
- **Suspected pregnancies can also be reported via the Malta Medicines Authority website.**

3.3 Men

- In view of the expected teratogenic risk of pomalidomide, foetal exposure should be avoided.
- Inform your patient about the effective contraceptive methods that his female partner can use.

Pomalidomide is present in human semen during treatment. 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 her doctor immediately. It is recommended that she be referred to a physician specialized in teratology for evaluation and advice.

Male patients should not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days following discontinuation of pomalidomide.

If the partner of a male patient taking pomalidomide Rowex becomes pregnant, then he must inform his prescriber immediately. Then:

- **Refer the female partner to a physician specialised or experienced in dealing with teratology for advice and evaluation.**
- **Notify the relevant Marketing Authorisation Holder Risk Management (see section 10.0 for contact details) immediately of all such occurrences. Please also complete the Pregnancy Reporting Form for the relevant Marketing Authorisation Holder. The relevant Marketing Authorisation Holder will wish to follow-up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.**
- **Suspected pregnancies can also be reported via the Malta Medicines Authority website.**

3.4 Advice for all Patients

All patients should be advised not to donate blood during treatment (including dose interruptions) and for at least 7 days after cessation of treatment with pomalidomide. If your patient discontinues therapy, or if there are any unused capsules at the end of their treatment, they must return any unused pomalidomide to the pharmacist.

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

3.5 Points to Consider for Handling the Medicinal Product: For Patients, Healthcare Professionals and Caregivers

Please refer to the SmPC for the pomalidomide product you are handling for specific handling advice.

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.

Care must be taken when removing capsules from the blister packaging to ensure that capsules are not broken. Please refer the patient to the package leaflet that comes with the medicine for instructions on how to remove the capsule from the blister to reduce the risk of damage to the capsule.

Healthcare professionals 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 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.

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 below)
- Place gloves in sealable plastic polyethylene bag and dispose 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 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.

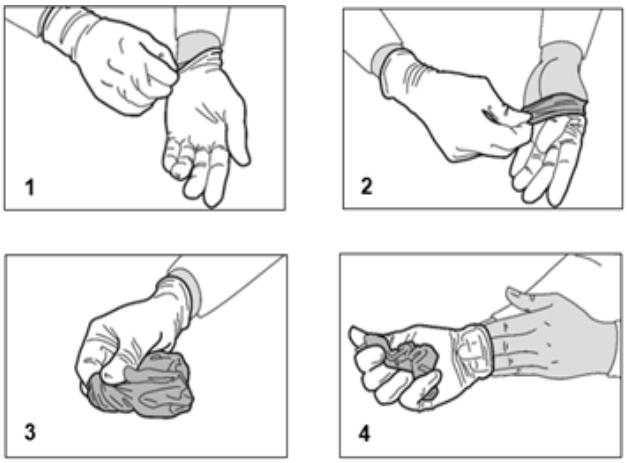
- If capsules are crushed or broken, dust containing drug substance may be released. Avoid dispersing the powder and avoid breathing on or inhaling the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise entry of powder into the air. Add excess liquid to allow the material to enter solution. After handling, clean the area thoroughly with soap and water 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 relevant Marketing Authorisation Holder (see section 10 for contact details)

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.



4.0 The Prescribers guide to Prescribing and Dispensing pomalidomide

Pomalidomide treatment must be initiated and monitored under the supervision of physicians with expertise in managing immunomodulatory or chemotherapeutic agents.

4.1 Maximum Prescription Lengths

Prescriptions for women of childbearing potential can be for a maximum duration of treatment of 4 weeks according to the approved indications' dosing regimens, and prescriptions for all other patients can be for a maximum duration of treatment of 12 weeks and continuation of treatment requires a new prescription

4.2 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 guide and the SmPC.
- Obtain written confirmation (using the Risk Awareness Form for the appropriate patient category) that they have received and understood this information, and provide the patient with a copy.
- Ensure that your patient is using the appropriate contraceptive measures, if relevant.
- Perform a pregnancy test (if appropriate) before initiating treatment.

4.3 Subsequent Prescriptions

• Before issuing subsequent prescriptions you must:

  – Ensure your patient continues to understand the risks of pomalidomide therapy.

  – Ensure that your patient is continuing to use the appropriate contraceptive measures, if relevant.

  – Perform a pregnancy test, if relevant.

All prescribers must have read and understood the information contained within the Healthcare Professionals' Information Guide before prescribing pomalidomide.

4.4 Prescription Authorisation Form (PAF)

Every prescription for pomalidomide must be accompanied by a completed Prescription Authorisation Form

The prescriber must confirm the following on the Prescription Authorisation Form:

- Patient initials, date of birth and the indication for which pomalidomide is being prescribed.
- Name of treating hospital, prescriber name, supervising physician name, signature and date.

- Confirmation that they have provided counselling on the teratogenic risk of pomalidomide and the required contraceptive measures for women of childbearing potential and male patients.
- Whether the patient is male, a woman of childbearing potential or a woman of non-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 the prescription.
- That the Risk Awareness Form has been completed and signed by the patient.
- That the prescriber has read and understood the contents of the Healthcare Professional's Information Guide.
- The information provided on this PAF is accurate, complete and in accordance with the requirements of the Pregnancy Prevention Programme for pomalidomide
- That treatment has been initiated by and is monitored under the supervision of a physician with expertise in managing immunomodulatory or chemotherapeutic agents.

If any information is missing, contact the prescriber for verification prior to dispensing.

4.5 Dispensing Advice

For women of childbearing potential:

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

For males and women of non-childbearing potential:

- Prescriptions of pomalidomide should be limited to a maximum duration of 12 consecutive weeks and continuation of treatment requires a new prescription.

For all patients:

- Please ensure that you dispense Pomalidomide blisters intact. Capsules must not be removed from blisters and packaged into bottles.
- Instruct patients to return any unused pomalidomide capsules to the pharmacy. Pharmacies must accept any unused pomalidomide capsules returned by patients for destruction and follow Good Pharmacy Practice guidelines for destruction of dangerous medicines.

Please ensure that all pharmacists within your pharmacy are educated about and familiar with the requirements for the Pregnancy Prevention Programme and the dispensing procedures for pomalidomide

5.0 Follow-up Assessment of the Effectiveness of the Programme and monitoring of off-label use

The terms of the pomalidomide Marketing Authorisation requires the Marketing Authorization Holder 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 foetal exposure to pomalidomide as well as to monitor for off-label use.

It is therefore critical for prescribers and pharmacies to ensure that all documentation associated with the Pregnancy Prevention Programme is completed accurately, in the interest of patient safety.

6.0 Other selected Risks of Pomalidomide

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 the SmPC (Section 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 thrombocytopenia, relate to the use of pomalidomide within its licensed indication. There is currently insufficient evidence regarding safety and efficacy in any other indication. For further information about the appropriate use and safety profile of pomalidomide, please refer to the SmPC.

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

61 Risk of Thrombocytopenia and Cardiac Failure with Pomalidomide

611 Thrombocytopenia

Thrombocytopenia is one of the major dose-limiting toxicities of treatment with pomalidomide. It is therefore encouraged to monitor complete blood counts (CBC) - 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 table below:

Dose Modification of 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 platelet count must be ≥50 x 10^9/L.

612 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).

613 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.

7.0 Reporting Adverse Events, Suspected and Confirmed Pregnancies, and Foetal Exposures

The safe use of pomalidomide is of paramount importance.

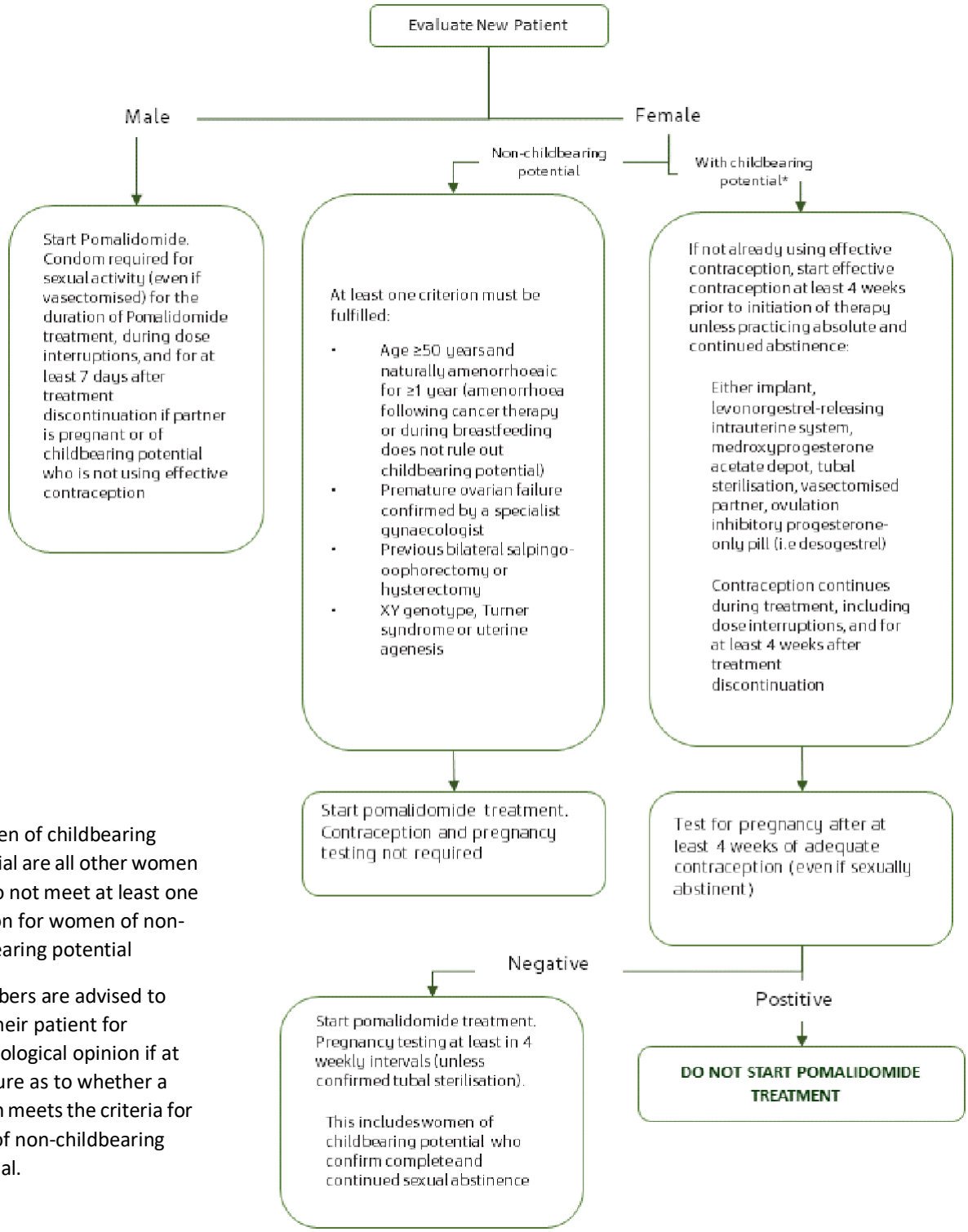
Adverse Events (and cases of suspected or confirmed pregnancy or foetal exposure) should be reported. Pregnancy Reporting forms can be found on the Malta Medicines Authority website, and should be forwarded to Malta Medicines Authority and to the relevant Marketing Authorisation Holder as below:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta
Website:
www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt

OR

Marketing Authorisation Holder:
Rowex Limited
Tel: 0877941968
Email: adverse.event.ireland@sandoz.net

8.0 Description of the Pregnancy Prevention Programme and Patient Categorisation Algorithm



*Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential

Prescribers are advised to refer their patient for gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

9.0 Contact Details

Risk Management

For information and questions on the Risk Management of Pomalidomide, the Pregnancy Prevention Programme, please contact the relevant Marketing Authorisation Holder, please see contact details below.

Rowex Ltd

Email: mi.ireland@sandoz.net

Tel: 0877941968

Medical Information and Adverse Event

To report any Adverse Events or suspected pregnancies, or to obtain Medical Information on the respective medicinal product from the relevant Marketing Authorisation Holder, please see contact details below.

Rowex Ltd

Email: mi.ireland@sandoz.net

Tel: 0877941968

Data Protection Contact Details

Please see below contact details for data protection queries for the relevant Marketing Authorisation Holder.

Rowex Ltd

Email: mi.ireland@sandoz.net