POMAGEN (pomalidomide)

Pomagen Healthcare Professional Information Pack

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Indications

Multiple myeloma

- Pomagen in combination therapy 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.

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

Introduction

- Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. In rats and rabbits, pomalidomide was found to be teratogenic when administered during the period of major organogenesis. In a rat embryofoetal developmental toxicity study, malformations including the absence of urinary bladder, absence of thyroid gland, and fusion and misalignment of lumbar and thoracic vertebral elements were observed at all tested dosage levels (25, 250, and 1000 mg/kg/day). In rabbits, increased cardiac anomalies were seen at all dosages ranging from 10 to 250 mg/kg/day, with significant increases at 250 mg/kg/day. At 250 mg/kg/day, foetal malformations included limb anomalies and associated skeletal malformations, moderate dilation of the lateral ventricle in the brain, abnormal placement of the right subclavian artery, absent intermediate lobe in the lungs, low-set kidney, altered liver morphology, incompletely or not ossified pelvis, increased average for supernumerary thoracic ribs and a reduced average for ossified tarsals. If pomalidomide is taken during pregnancy, a teratogenic effect can be expected.

- Pomalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Programme described in this brochure are carried out. Pomalidomide is also contraindicated in male patients unable to follow or comply with the required contraceptive measures described in this brochure.

- All men and all women of childbearing potential should undergo counselling of the need to avoid pregnancy (checklists for counselling are provided with this pack).

- Patients should be capable of complying with the requirements of safe use of pomalidomide.

- Patients should be provided with the Pomagen Patient Brochure and Pomagen Patient Agreement Form.

Additional precautions

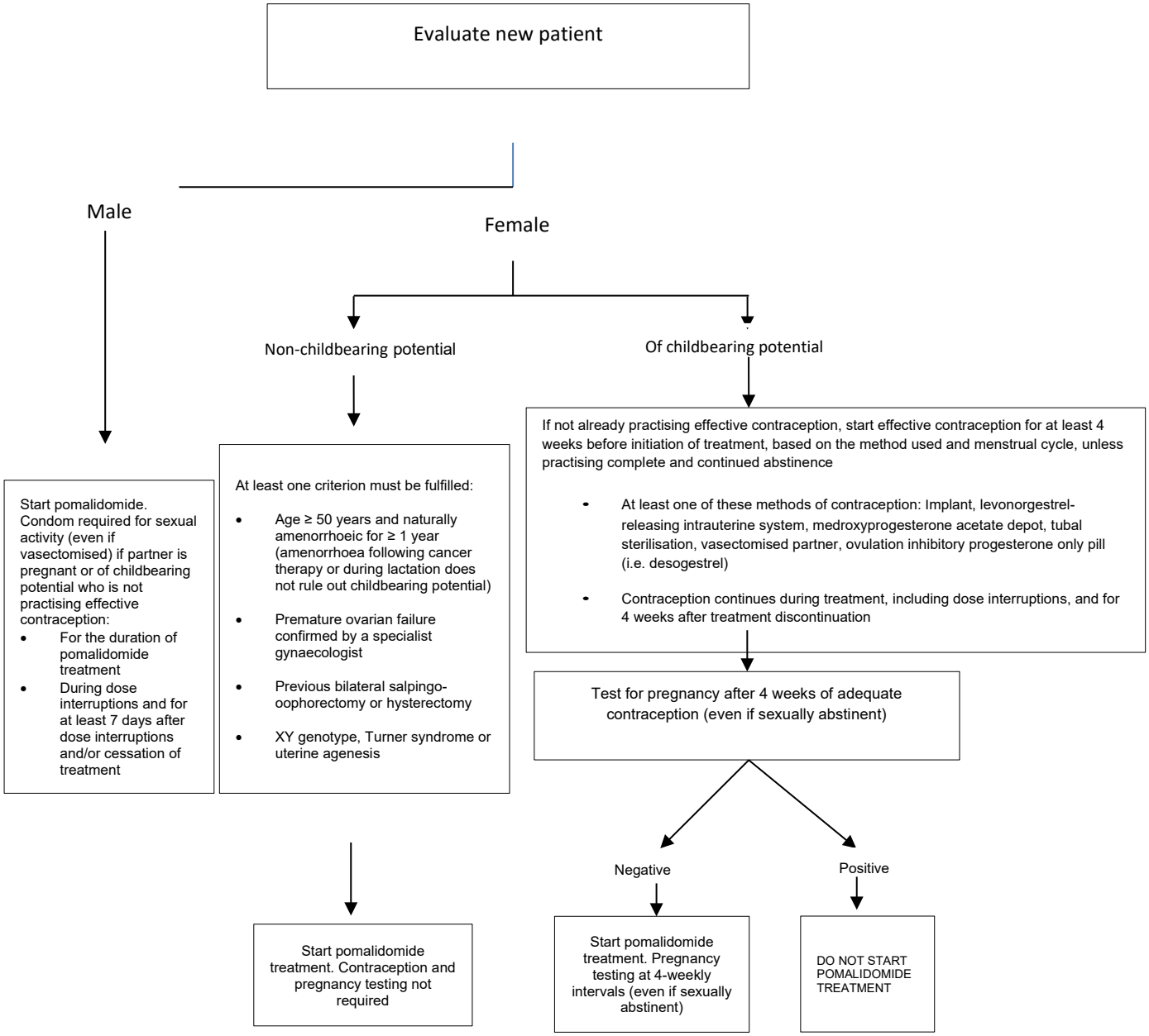
- Patients should be instructed never to give this medicinal product to another person and to return any unused capsules to their pharmacist at the end of treatment.

- Patients should not donate blood, semen or sperm during treatment (including during dose interruptions) and for at least 7 days following discontinuation of pomalidomide.

- 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.

Pregnancy Prevention Programme

- The Pregnancy Prevention Programme is set out in the following Algorithm:



• Criteria for non-childbearing potential in women

A female patient or a female partner of a male patient is considered not to have childbearing potential if she meets at least one of the following criteria:

- Age ⩾50 years and naturally amenorrhoeic for ⩾1 year (Amenorrhoea following cancer therapy or during breast-feeding 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.

You are advised to refer your patient for a gynaecological opinion if you are unsure whether or not she meets these criteria.

Safety Advice for Women of Childbearing Potential

Counselling

For women of childbearing potential, pomalidomide is contraindicated unless all of the following are met:

- She understands the expected teratogenic risk to the unborn child.
- She understands the need for effective contraception, without interruption, at least 4 weeks before starting treatment, throughout the entire duration of treatment, and at least 4 weeks after the end of treatment.
- Even if a woman of childbearing potential has amenorrhea she must follow all the advice on effective contraception.
- She should be capable of complying with effective contraceptive measures.
- She is informed and understands the potential consequences of pregnancy and the need to rapidly consult a healthcare professional if there is a risk of pregnancy.
- She understands the need to commence the treatment as soon as pomalidomide is dispensed following a negative pregnancy test.
- She understands the need and accepts to undergo pregnancy testing at least every 4 weeks except in case of confirmed tubal sterilisation.
- She acknowledges that she understands the hazards and necessary precautions associated with the use of pomalidomide.

Pregnancy testing

Medically supervised pregnancy tests with a minimum sensitivity of 25 mIU/mL must be performed for women of childbearing potential as outlined below. This requirement includes women of childbearing potential who practise absolute and continuous abstinence. Ideally, pregnancy testing, issuing of prescription and dispensing should occur on the same day. Otherwise,

dispensing of pomalidomide to women of childbearing potential should occur within 7 days of the prescription.

- *Prior to starting treatment*

  A medically supervised pregnancy test should be performed during the consultation, when pomalidomide is prescribed, or in the 3 days prior to the visit to the prescriber once the patient has been using effective contraception for at least 4 weeks. The test should ensure the patient is not pregnant when she starts treatment with pomalidomide.

- *Follow-up and end of treatment*

  A medically supervised pregnancy test should be repeated at least every 4 weeks, including at least 4 weeks after the end of treatment, except in the case of confirmed tubal sterilisation. These pregnancy tests should be performed on the day of the prescribing visit or in the 3 days prior to the visit to the prescriber.

Contraception

Women of childbearing potential 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 and even in case of dose interruption unless the patient commits to absolute and continuous abstinence confirmed on a monthly basis. If not established on effective contraception, the patient must be referred to an appropriately trained healthcare professional for contraceptive advice in order for contraception to 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 dexamtheasone, 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 4−6 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.

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.

Safety Advice for Men

For male patients taking pomalidomide, pharmacokinetic data has demonstrated that pomalidomide is present in human semen during treatment. As a precaution and taking into account special populations with potentially prolonged elimination time such as hepatic impairment, all male patients taking pomalidomide must meet the following conditions:

- He understands the expected teratogenic risk if engaged in sexual activity with a pregnant woman or a woman of childbearing potential.
- He understands the need for the use of a condom if engaged in sexual activity with a pregnant woman or a woman of childbearing potential not using effective contraception, throughout treatment duration, during dose interruption and for at least 7 days after dose interruptions and/or cessation of treatment. This includes vasectomised males who should wear a condom if engaged in sexual activity with a pregnant woman or a woman of childbearing potential as seminal fluid may still contain pomalidomide in the absence of spermatozoa.
- He understands that if his female partner becomes pregnant whilst he is taking pomalidomide or within 7 days after he has stopped taking pomalidomide, he should inform his treating physician immediately and that it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice.

In the event of a suspected pregnancy in the female patient or female partner of a male patient

- ✓ Stop treatment if female patient.
- ✓ Refer the patient or female partner to a physician specialised or experienced in teratology for evaluation and advice.
- ✓ Notify Lotus' representative of all such occurrences using the Pomagen Pregnancy Reporting Form included in this pack. Lotus wishes to follow-up with you on the progress of all pregnancies.
- ✓ Report the event to the Health Sciences Authority (HSA) as per guidelines for adverse event reporting.

Reporting of Adverse Reactions

Local Country Contact Details

The safe use of pomalidomide is of paramount importance. As part of Lotus' ongoing safety monitoring, the company wishes to learn of adverse reactions that have occurred during the use of pomalidomide. Please report adverse events to Lotus' representative via the following contact details:

Euro Asia Medico Pte. Ltd.
Email: **rmp@eamedico.com**

Health Sciences Authority (HSA)

Adverse events should also be reported to HSA via their online reporting portal at www.hsa.gov.sg/adverse-events.

Enclosures

- ✓ Pomagen Communication Plan
- ✓ Pomagen Prescriber Enrollment Form
- ✓ Pomagen Pharmacy Enrollment Form
- ✓ Pomagen Patient Agreement Form
- ✓ Pomagen Pregnancy Reporting Form
- ✓ Pomagen Patient Brochure
- ✓ Pomagen Patient Information Leaflet
- ✓ Pomagen Package Insert

This document has been approved by HSA on 12 April 2024.

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