

Direct Healthcare Professional Communication

We wish to inform you about important aspects in the clinical use of *IMNOVID* (pomalidomide) which has now received market authorisation in combination with dexamethasone for 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.

The content of this communication has been agreed with the Committee for Medicinal Products for Human Use (CHMP) and Medicines Authority

Pregnancy Prevention Programme

- Pomalidomide is structurally related to thalidomide. Thalidomide is a known human teratogen that causes severe life-threatening birth defects. Pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. If pomalidomide is taken during pregnancy, a teratogenic effect in humans is expected.
- Pomalidomide is contraindicated for use in pregnancy. It is also contraindicated in women of childbearing potential unless all the conditions of the pomalidomide Pregnancy Prevention Programme are met.

Multiple Myeloma is a disease of a predominantly elderly population. However, women of childbearing potential could be part of the patient population. We wish to draw your attention to the conditions of the Pregnancy Prevention Programme that must be complied with in this small specific patient population.

Further information on the Pregnancy Prevention Programme and recommendations

Women of childbearing potential

All women of childbearing potential must:

- Receive counselling regarding the expected teratogenic risk of pomalidomide to the unborn child and the need to avoid pregnancy
- Use one effective method of contraception for 4 weeks before therapy, during therapy, during dose interruptions and 4 weeks after therapy has finished, unless the woman commits to absolute and continued abstinence confirmed on a monthly basis.
- Have a medically supervised negative pregnancy test once she has been established on contraception for 4 weeks, at 4 weekly intervals during therapy and 4 weeks after the end of therapy, except in the case of confirmed tubal sterilisation. This pregnancy test requirement includes women of childbearing potential who practice absolute and continued abstinence.

- The following can be considered to be examples of effective 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
 - Ovulatory 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.

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.

Section 4.4 of the enclosed SmPC provides further guidance on the definition of a woman of childbearing potential, counselling, effective contraception and pregnancy testing.

The Risk Management Program training kit contains the following documents:

- **Pomalidomide Prescribing Information (EU SmPC)**
- **Pomalidomide HCP booklet**
- **Patient booklet (Male, WCBP, WNCBP)**
- **Treatment Initiation Form (Male, WCBP, WNCBP)**
- **Patient Card**
- **Pomalidomide's potential for human birth defects**
- **Prevention of pomalidomide fetal exposure and categorizing a patient's risk category**
- **Adverse Event form and Adverse Event reporting**
- **Pregnancy Capture form and reporting of suspected fetal exposure**
- **Order form (also used to enrol patient into NPP)**
- **Training Acknowledgement Form**

Prescribing, dispensing Healthcare professionals and patients are enrolled in the PPP after undergoing local training.

All purchase orders for IMNOVID must be prescribed by enrolled specialists for enrolled patients and dispensed by enrolled healthcare professionals.

Pregnancy capture forms are available in the Healthcare Professional Kit and may be requested by email to pv@ammangion.com.mt.

If pregnancy does occur in your patient whilst she is receiving pomalidomide, treatment must be stopped and the patient be referred to a physician specialised or experienced in teratology for evaluation and advice. If pregnancy occurs in a partner of a male patient while he is taking pomalidomide or 1 week after he has stopped taking pomalidomide, he should inform his treating physician immediately and it is recommended to refer the female partner to a physician specialised or experienced in teratology for evaluation and advice.

You are also requested to notify AM Mangion Ltd of all such occurrences.

Men

Pomalidomide is present in semen during treatment. Therefore, all male patients should use condoms throughout treatment duration, during dose interruption and for 1 week after cessation of treatment if their partner is pregnant or of childbearing potential and is not using effective contraception.

Patients should not donate sperm during treatment (including during dose interruptions) or for 1 week following discontinuation of pomalidomide

All patients

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

Patients should not donate blood during therapy (including during dose interruptions) and for 1 week following the discontinuation of pomalidomide.

Call for reporting

Any ADR's should be reported to the Pharmacovigilance department at AM Mangion Ltd. "Mangion Building", New Street off Valletta Road, Luqa, LQA6000 or via email on pv@ammangion.com.mt. Alternatively, you may use the 24 hour PV line on +23976333 or fax 23976123.

You may also report ADR's to Medicines Authority on their website <http://www.medicinesauthority.gov.mt/adrportal> or by post at Medicines Authority 203, Level 3, Rue D'Argens, Gzira GZR 1368, Malta.

Company Contact Point

If you have any further questions, require further information or would like to request a Educational Healthcare Professional Kit for Imnovid®, please contact your local Celgene representative at AM Mangion Ltd. "Mangion Building", New Street off Valletta Road, Luqa, LQA6000 or via email on pv@ammangion.com.mt. Alternatively, you may use the 24 hour PV line on +23976333 or fax 23976123.

Annexes

Summary of Product Characteristics

