LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

# Summary Public Assessment Report

# Lenalidomide Orion (lenalidomide)

# SE/H/2033/01-05/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

# Summary Public Assessment Report

Lenalidomide Orion
lenalidomide

Capsule, hard, 5 mg, 10 mg, 15 mg, 20 mg, 25 mg

This is a summary of the public assessment report (PAR) for Lenalidomide Orion. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

**What is Lenalidomide Orion and what is it used for?**

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Revlimid.

The product can be used in adults for:

- multiple myeloma
- myelodysplastic syndromes
- mantle cell lymphoma
- follicular lymphoma.

**How does Lenalidomide Orion work?**

The active substance lenalidomide, is an immunomodulator. This means that it affects the activity of the body's natural defences (the immune system). Lenalidomide works in several ways: it blocks the development of abnormal cells, prevents the growth of blood vessels within tumours and also stimulates specialised cells of the immune system to attack the abnormal cells.

**How is Lenalidomide Orion used?**

The pharmaceutical form is capsule, hard for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

**What benefits of Lenalidomide Orion have been shown in studies?**

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Revlimid.

**What are the possible side effects from Lenalidomide Orion?**

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

**Why is Lenalidomide Orion approved?**

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Revlimid. Therefore, the Swedish Medical Products Agency decided that, as for Revlimid, the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Lenalidomide Orion?"

**What measures are being taken to ensure the safe and effective use of Lenalidomide Orion?**

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

**Additional risk minimisation measures (including educational material)**
The applicant has proposed the following key elements. These are identical, where relevant, with the reference product Revlimid and are acceptable.

1. The MAH shall agree the details of a controlled distribution system with the National Competent Authorities and must implement such programme nationally to ensure that:

- Prior to launch, all doctors who intend to prescribe Lenalidomide Orion and all pharmacists who may dispense Lenalidomide Orion receive a Direct Healthcare Professional Communication as described below.
- Prior to prescribing (and where appropriate, and in agreement with the national competent authority, prior to dispensing) all healthcare professionals who intend to prescribe (and dispense) Lenalidomide Orion are provided with a physician information pack containing the following:
    - o Educational health care professional's kit
    - o Educational brochures for patients
    - o Patient cards
    - o Summary of product characteristics (SmPC) and package leaflet and labelling.

2. The MAH shall implement a pregnancy prevention programme (PPP) in each Member State. Details of the PPP should be agreed with the National Competent Authorities in each Member State and put in place prior to the launch of the product.

3. The MAH should agree the final text of the Direct Healthcare Professional Communication and the physician information pack contents with the National Competent Authority in each Member State and ensure that the materials contain the key elements as described below.

4. The MAH should agree on the implementation of the patient card system in each Member State.

**Key messages of the additional risk minimisation measures**

***Direct Healthcare Professional Communications***
The Direct Healthcare Professional Communication prior to launch shall consist of two parts:

- National specific requirements agreed with the National Competent Authority regarding:
    - o Distribution of the product
    - o To ensure that all appropriate measures have been performed prior to Lenalidomide Orion being dispensed

***The Educational Healthcare Professional's Kit***

The Educational Health Care Professional's Kit shall contain the following elements:

- Brief background on lenalidomide and its licensed indication
- Posology
- Maximum duration of treatment prescribed according to the approved indications dosing regimens
  - 4 weeks treatment for women with childbearing potential
  - 12 weeks treatment for men and women without childbearing potential
- The need to avoid foetal exposure due to teratogenicity of lenalidomide in animals and the expected teratogenic effect of lenalidomide in humans including a summary of the results of study CC-5013-TOX-004
- Guidance on handling the blister or capsule of Revlimid for healthcare professionals and caregivers
- Obligations of the health care professional in relation to the prescribing of Lenalidomide Orion
  - Need to provide comprehensive advice and counselling to patients
  - That patients should be capable of complying with the requirements for the safe use of Lenalidomide Orion
  - Need to provide patients with appropriate patient educational brochure and patient card
- Safety advice relevant to all patients
  - Disposal of unwanted medicine
  - Local country specific arrangements for a prescription for Lenalidomide Orion to be dispensed
  - Description of risk of tumour flare reaction in MCL patients
  - Description of the risk of progression to AML in MDS patients including incidence rates from clinical trials
  - Description of risk of SPM
- Description of the PPP and categorisation of patients based on sex and childbearing potential
  - Algorithm for implementation of PPP
  - Definition of women of childbearing potential (WCBP) and actions the physician should take if unsure
- Safety advice for women of childbearing potential
  - The need to avoid foetal exposure
  - Description of the PPP
  - Need for adequate contraception (even if woman has amenorrhoea) and definition of adequate contraception
  - Pregnancy test regime
    - Advice on suitable tests
    - Before commencing treatment
    - During treatment based on method of contraception
    - After finishing treatment
  - Need to stop Lenalidomide Orion immediately upon suspicion of pregnancy
  - Need to tell treating doctor immediately upon suspicion of pregnancy
- Safety advice for men
  - The need to avoid foetal exposure
  - The need to use condoms if sexual partner is pregnant or a WCBP not using effective contraceptions (even if man has had a vasectomy)
    - During Lenalidomide Orion treatment
    - For at least 7 days following final dose.
  - That if his partner becomes pregnant whilst he is taking Lenalidomide Orion or shortly after he has stopped taking Lenalidomide Orion he should inform his treating doctor immediately

- Requirements in the event of pregnancy
  - Instructions to stop Lenalidomide Orion immediately upon suspicion of pregnancy, if female patient

- Need to refer to physician specialised or experienced in dealing with teratology and its diagnosis for evaluation and advice
- Local contact details for reporting of any suspected pregnancy
- Pregnancy reporting form

- Check list for physicians ensuring that patients receive the appropriate counselling concerning the treatment, contraceptive methods and pregnancy prevention appropriate for their sex and childbearing status at treatment initiation.
- Adverse event reporting forms

***Educational Brochures for patients***

- The Educational brochures for patients should be of 3 types:
  - Brochure for women patients of childbearing potential
  - Brochure for women patients who are not of childbearing potential
  - Brochure for male patients
- All patient brochures should contain the following elements:
  - That lenalidomide is teratogenic in animals and is expected to be teratogenic in humans
  - Description of the patient card and its necessity
  - Disposal of unwanted medicine
  - Guidance on handling lenalidomide for patients, caregivers and family members
  - National or other applicable specific arrangements for a prescription for Lenalidomide Orion to be dispensed
  - That the patient should not give Lenalidomide Orion to any other person
  - That the patient should not donate blood during therapy (including during dose interruptions) and for at least 7 days after discontinuation of Lenalidomide Orion treatment
  - That the patient should tell their doctor about any adverse events

The following information should also be provided in the appropriate brochure:

- Brochure for women patients with childbearing potential
  - The need to avoid foetal exposure
  - Description of the PPP
  - Need for adequate contraception and definition of adequate contraception
  - Pregnancy test regime
    - Before commencing treatment
    - During treatment, at least every 4 weeks except in case of confirmed tubal sterilization
    - After finishing treatment
  - The need to stop Lenalidomide Orion immediately upon suspicion of pregnancy
  - The need to contact their doctor immediately upon suspicion of pregnancy
- Brochure for male patients
  - The need to avoid foetal exposure
  - The need to use condoms if sexual partner is pregnant or a WCBP not using effective contraceptions (even if man has had vasectomy)
    - During Lenalidomide Orion treatment
    - For at least 7 days following final dose
  - That if his partner becomes pregnant he should inform his treating doctor immediately
  - That he should not donate semen or sperm during therapy (including during dose interruptions) and at least for 7 days after discontinuation of Lenalidomide Orion treatment
- Patient Card

The patient card shall contain the following elements:

- Verification that appropriate counselling has taken place
- Documentation of childbearing status potential
- Pregnancy test dates and results

**Other information about Lenalidomide Orion**

The full PAR for Lenalidomide Orion can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Lenalidomide Orion, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-08.