COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Lenalidomide Teva 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg, hard capsules

(lenalidomide)

NL/H/4067/001-007/DC

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Active substance: lenalidomide

This is a summary of the public assessment report (PAR) for Lenalidomide Teva. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Lenalidomide Teva.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lenalidomide Teva and what is it used for?
Lenalidomide Teva 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 is used in adults for multiple myeloma, a cancer of a type of white blood cells called plasma cells:

- on its own, in adults who have had a stem cell transplant (a procedure where the patient's bone marrow is cleared of cells and replaced by stem cells from a donor) to stop the progression of the cancer;
- in combination therapy, for the treatment of adults with previously untreated multiple myeloma, who cannot have stem cell transplantation;
- in combination with dexamethasone, in adults whose disease has been treated at least once in the past.

How does this medicine work?
The active substance in Lenalidomide Teva, lenalidomide, is an immunomodulating agent. This means that it affects the activity of the immune system (the body's natural defences). Lenalidomide works in a number of different 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 this medicine used?
The pharmaceutical form of Lenalidomide Teva is a hard capsule and the route of administration is oral. The medicine can only be obtained with a prescription.

Lenalidomide Teva is taken in repeated 28 day cycles: the patient takes the medicine once a day on certain days over 28 days. Depending on the day, the patient may take one or more medicines or may not take any medicines.

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

How has this medicine been studied?
Because Lenalidomide Teva is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Revlimid. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Lenalidomide Teva is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent/be comparable to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for reference medicine, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 for Lenalidomide Teva, 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.

The company that markets Lenalidomide Teva will provide educational material for all doctors who are expected to prescribe this medicine to provide guidance on how it should be used and monitored. Patients will also receive an educational brochure containing a brochure and a patient card.

Other information about this medicine
In the Netherlands, the marketing authorisation for Lenalidomide Teva 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, 20 mg, 25 mg, hard capsules was granted on 20 November 2018.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Lenalidomide Teva, read the package leaflet

(https://mri.cts-mrp.eu/Human/Downloads/NL_H_4067_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in September 2018.