Summary Public Assessment Report

Generics

Lenalidomide Pharmascience
lenalidomide

IS/H/0386/001-007/DC

Date: 05.02.2021

Summary Public Assessment Report

Generics

Lenalidomide Pharmascience

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

This is a summary of the public assessment report (PAR) for Lenalidomide Pharmascience. It explains how Lenalidomide Pharmascience 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 Pharmascience.

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

What is Lenalidomide Pharmascience and what is it used for?

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

Lenalidomide Pharmascience is used in the treatment of adult with multiple myeloma or follicular lymphoma.

Multiple myeloma is a type of cancer which affects a certain kind of white blood cell, called the plasma cell. These cells collect in the bone marrow and divide, becoming out of control. This can damage the bones and kidneys. Multiple myeloma generally cannot be cured. However, the signs and symptoms can be greatly reduced or disappear for a period of time. This is called a 'response'.

Follicular lymphoma (FL) is a slow growing cancer that affects the B-lymphocytes. These are a type of white blood cells that help your body fight infection. When you have FL, too many of these B-lymphocytes may collect in your blood, bone marrow, lymph nodes and spleen.
Lenalidomide Pharmascience is taken together with another medicine called 'rituximab' for the treatment of adult patients with previously treated follicular lymphoma.

How does Lenalidomide Pharmascience work?

Lenalidomide Pharmascience works by affecting the body's immune system and directly attacking the cancer. It works in a number of different ways:
- by stopping the cancer cells developing
- by stopping blood vessels growing in the cancer
- by stimulating part of the immune system to attack the cancer cells.

How is Lenalidomide Pharmascience used?
The pharmaceutical form of Lenalidomide Pharmascience is hard capsule and the route of administration is oral.

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

Lenalidomide Pharmascience must be given to you by healthcare professionals with experience in treating multiple myeloma or FL. Lenalidomide Pharmascience is taken in treatment cycles, each cycle lasting 21 or 28 days. You should continue the cycles of treatment until your doctor tells you to stop. If you are taking Lenalidomide Pharmascience in combination with other medicines, you should refer to the package leaflets for these medicines for further information on their use and effects.

The medicine can only be obtained with a prescription.

What benefits of Lenalidomide Pharmascience have been shown in studies?
Because Lenalidomide Pharmascience 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.

The company provided data from the published literature on lenalidomide.

What are the possible side effects of Lenalidomide Pharmascience?

Because Lenalidomide Pharmascience 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 restrictions, see the package leaflet.

Why is Lenalidomide Pharmascience approved?

It was concluded that, in accordance with EU requirements, Lenalidomide Pharmascience has been shown to have comparable quality and to be bioequivalent/be comparable to Revlimid. Therefore, the Icelandic Medicines Agency decided that, as for reference medicine called Revlimid, 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 Lenalidomide Pharmascience?

A risk management plan has been developed to ensure that Lenalidomide Pharmascience 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 Pharmascience, 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.

Other information about Lenalidomide Pharmascience

The marketing authorisation for Lenalidomide Pharmascience was granted on 11.09.2020.

The full PAR for Lenalidomide Pharmascience can be found on the website MRIndex. For more information about treatment with Lenalidomide Pharmascience, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in January 2021.