LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Lenalidomide Newbury (lenalidomide)

SE/H/2413/002,004,005,007

This module reflects the scientific discussion for the approval of Lenalidomide Newbury. The Summary Public Assessment Report was written in December 2021 by the previous RMS (IS) after initial procedure (IS/H/0468/001-007/DC). RMS transfer from (IS) to SE was completed 2023-02-23.

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

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Generics

Lenalidomide Newbury
lenalidomide

IS/H/0468/001-007/DC

Date: 29.12.2021

Summary Public Assessment Report

Generics

General guidance: In principle information from the PL should be included and standard texts/sentences should be used where possible.

Lenalidomide Newbury

Lenalidomide, hard capsule, 2.5 mg, 5.0 mg, 7.5 mg, 10 mg, 15 mg, 20 mg and 25 mg

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

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

What is Lenalidomide Newbury and what is it used for?

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

Lenalidomide Newbury is used in adults for:

- Multiple myeloma
- Myelodysplastic syndromes
- Mantle cell lymphoma
- Follicular lymphoma

Multiple myeloma

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'.

<u>Newly diagnosed multiple myeloma in patients who have had a bone marrow transplant</u>

[Product Name] is used on its own as maintenance therapy after patients have recovered enough following a bone marrow transplant.

<u>Newly diagnosed multiple myeloma – in patients who cannot have a bone marrow transplant</u>

[Product Name] is taken with other medicines. These may include:

- a chemotherapy medicine called 'bortezomib'
- an anti-inflammatory medicine called 'dexamethasone'
- a chemotherapy medicine called 'melphalan' and
- an immunosuppressant medicine called 'prednisone'.

You will take these other medicines at the start of treatment and then continue to take [Product Name] on its own.

If you are aged 75 years or older or have moderate to severe kidney problems – your doctor will check you carefully before starting treatment.

Multiple myeloma – in patients who have had treatment before
[Product Name] is taken together with an anti-inflammatory medicine called ‘dexamethasone’. Lenalidomide can stop the signs and symptoms of multiple myeloma getting worse. It has also been shown to delay multiple myeloma from coming back following treatment.

Myelodysplastic syndromes (MDS)
MDS are a collection of many different blood and bone marrow diseases. The blood cells become abnormal and do not function properly. Patients can experience a variety of signs and symptoms including a low red blood cell count (anaemia), the need for a blood transfusion, and be at risk of infection.
[Product Name] is used alone to treat adult patients who have been diagnosed with MDS, when all of the following apply:
- you need regular blood transfusions to treat low levels of red blood cells (‘transfusion-dependent anaemia’)
- you have an abnormality of cells in the bone marrow called an ‘isolated deletion 5q cytogenetic abnormality’. This means your body does not make enough healthy blood cells
- other treatments have been used before, are not suitable or do not work well enough.

[Product Name] can increase the number of healthy red blood cells that the body produces by reducing the number of abnormal cells:
- this can reduce the number of blood transfusions needed. It is possible that no transfusions will be needed.

Mantle cell lymphoma (MCL)
MCL is a cancer of part of the immune system (the lymph tissue). It affects a type of white blood cell called ‘B-lymphocytes’ or B-cells. MCL is a disease where B-cells grow in an uncontrolled way and build up in the lymph tissue, bone marrow or blood.
[Product Name] is used alone to treat adult patients who have previously been treated with other medicines.

Follicular lymphoma (FL)
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.
[Product name] is taken together with another medicine called ‘rituximab’ for the treatment of adult patients with previously treated follicular lymphoma.

How does Lenalidomide Newbury work?
Lenalidomide Newbury 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 Newbury used?
The pharmaceutical form of Lenalidomide Newbury 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 Newbury must be given to you by healthcare professionals with experience in treating multiple myeloma, MDS, MCL or FL.

- When Lenalidomide Newbury is used to treat multiple myeloma in patients who cannot have a bone marrow transplant or have had other treatments before, it is taken with other medicines.
- When Lenalidomide Newbury is used to treat multiple myeloma in patients who have had a bone marrow transplant or to treat patients with MDS or MCL, it is taken alone.
- When Lenalidomide Newbury is used to treat follicular lymphoma, it is taken with another medicine called “rituximab”.

Lenalidomide Newbury is taken on certain days over 3 weeks (21 days).
- Every 21 days is called a ‘treatment cycle’.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.
- After completing every 21-day cycle, you should start a new ‘cycle’ over the next 21 days.

OR

Lenalidomide Newbury is taken on certain days over 4 weeks (28 days).
- Every 28 days is called a ‘treatment cycle’.
- Depending on the day of the cycle, you will take one or more of the medicines. However, on some days you do not take any of the medicines.
- After completing every 28-day cycle, you should start a new ‘cycle’ over the next 28 days.

The medicine can only be obtained with a prescription.

What benefits of Lenalidomide Newbury have been shown in studies?
Because Lenalidomide Newbury is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Revlimir. 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 Newbury?

Because Lenalidomide Newbury 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 Newbury approved?

It was concluded that, in accordance with EU requirements, Lenalidomide Newbury 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 Newbury?

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

The marketing authorisation for Lenalidomide Newbury was granted on 20.12.2021

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

This summary was last updated in 12.2021.