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Lenalidomide Mylan (*lenalidomide*)

An overview of Lenalidomide Mylan and why it is authorised in the EU

What is Lenalidomide Mylan and what is it used for?

Lenalidomide Mylan is a medicine used for the treatment of certain cancers affecting blood cells, namely multiple myeloma and follicular lymphoma.

In **multiple myeloma**, a cancer of a type of white blood cells called plasma cells, Lenalidomide Mylan is used:

- in adults with previously untreated (newly diagnosed) multiple myeloma, 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);
- in adults with previously untreated (newly diagnosed) multiple myeloma, who cannot have stem cell transplantation. It is used in combination with dexamethasone, or bortezomib and dexamethasone, or melphalan and prednisone;
- in adults whose disease has been treated at least once. It is used in combination with dexamethasone.

In **follicular lymphoma**, a blood cancer that affects a type of white blood cell called B lymphocytes, Lenalidomide Mylan is used in adults whose disease has come back after treatment or does not improve with treatment. It is used in combination with rituximab.

Lenalidomide Mylan contains the active substance lenalidomide and is a 'generic medicine'. This means that Lenalidomide Mylan contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Revlimid. For more information on generic medicines, see the question-and-answer document here.

How is Lenalidomide Mylan used?

Lenalidomide Mylan can only be obtained with a prescription and treatment should be supervised by doctors who have experience in the use of cancer medicines.

Lenalidomide Mylan is available as capsules of various strengths to be taken by mouth. Treatment is given in cycles, with the medicine being used once a day on certain days of the cycles. Treatment cycles are continued until the disease is no longer being controlled or side effects become

unacceptable. The dose depends on the disease it is being used for, the patient's overall health and blood test results. The dose may need to be reduced or treatment interrupted in case of certain side effects.

For more information about using Lenalidomide Mylan, see the package leaflet or contact your doctor or pharmacist.

How does Lenalidomide Mylan work?

The active substance in Lenalidomide Mylan, lenalidomide, is an immunomodulator. This means that it affects the activity of the immune system (the body's natural defences). 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 has Lenalidomide Mylan been studied?

Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Revlimid, and do not need to be repeated for Lenalidomide Mylan.

As for every medicine, the company provided studies on the quality of Lenalidomide Mylan. The company also carried out studies that showed that it is 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body and are therefore expected to have the same effect.

What are the benefits and risks of Lenalidomide Mylan?

Because Lenalidomide Mylan is a generic medicine and is bioequivalent to the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Lenalidomide Mylan authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Lenalidomide Mylan has been shown to have comparable quality and to be bioequivalent to Revlimid. Therefore, the Agency's view was that, as for Revlimid, the benefits of Lenalidomide Mylan outweigh the identified risks and it can be authorised for use in the EU.

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

The company that markets Lenalidomide Mylan will provide educational kits for healthcare professionals, and brochures for patients, explaining that the medicine can be harmful to the unborn child and detailing the steps that need to be taken for the medicine to be used safely. It will also supply cards to patients about the safety measures patients should take.

The company has also set up a pregnancy prevention programme in each member state and will collect information on the medicine's use outside its approved uses. The boxes containing Lenalidomide Mylan capsules also include a warning stating that lenalidomide can be harmful to the unborn child.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Lenalidomide Mylan have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Lenalidomide Mylan are continuously monitored. Side effects reported with Lenalidomide Mylan are carefully evaluated and any necessary action taken to protect patients.

Other information about Lenalidomide Mylan

Lenalidomide Mylan received a marketing authorisation valid throughout the EU on 18 December 2020.

Further information on Lenalidomide Mylan can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/lenalidomide-mylan. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 12-2020.