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Lenalidomide Krka d.d. (*lenalidomide*)

An overview of Lenalidomide Krka d.d. and why it is authorised in the EU

What is Lenalidomide Krka d.d. and what is it used for?

Lenalidomide Krka d.d. is a medicine used for the treatment of certain cancers and serious conditions affecting blood cells and bone marrow, namely multiple myeloma, myelodysplastic syndromes and follicular lymphoma.

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

- in adults with previously untreated (newly diagnosed) multiple myeloma, who have had an autologous stem cell transplant (a procedure where the patient's bone marrow is cleared of cells and replaced with the patient's own stem cells to form new bone marrow);
- in adults with previously untreated 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 **myelodysplastic syndromes**, a group of bone marrow disorders that cause anaemia (low red blood cell counts), Lenalidomide Krka d.d. is used in patients who need blood transfusions to manage their anaemia. It is used in patients with a genetic change (called deletion 5q) when other treatments are not adequate.

In **follicular lymphoma**, a blood cancer that affects a type of white blood cell called B lymphocytes, Lenalidomide Krka d.d. 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 Krka d.d. contains the active substance lenalidomide and is a 'generic medicine'. This means that Lenalidomide Krka d.d. 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.

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How is Lenalidomide Krka d.d. used?

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

Lenalidomide Krka d.d. 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 Krka d.d., see the package leaflet or contact your doctor or pharmacist.

How does Lenalidomide Krka d.d. work?

The active substance in Lenalidomide Krka d.d., 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 stimulates specialised cells of the immune system to attack the abnormal cells.

How has Lenalidomide Krka d.d. 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 Krka d.d.

As for every medicine, the company provided studies on the quality of Lenalidomide Krka d.d. 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 Krka d.d.?

Because Lenalidomide Krka d.d. 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 Krka d.d. authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Lenalidomide Krka d.d. 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 Krka d.d. 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 Krka d.d.?

The company that markets Lenalidomide Krka d.d. 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 and will collect information on the medicine's use outside its authorised uses. The boxes containing Lenalidomide Krka d.d. 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 Krka d.d. have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Lenalidomide Krka d.d.

Lenalidomide Krka d.d. received a marketing authorisation valid throughout the EU on 11 February 2021.

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

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