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Pomalidomide Krka (*pomalidomide*)

An overview of Pomalidomide Krka and why it is authorised in the EU

What is Pomalidomide Krka and what is it used for?

Pomalidomide Krka is a cancer medicine used to treat multiple myeloma (a cancer of the bone marrow). It is used in combination with bortezomib (another cancer medicine) and dexamethasone (an anti-inflammatory medicine) in adults who have received at least one treatment including lenalidomide (another cancer medicine).

It is also used in combination with dexamethasone in adults who have received at least two prior therapies, including both lenalidomide and bortezomib, and whose disease has worsened.

Pomalidomide Krka contains the active substance pomalidomide and is a 'generic medicine'. This means that Pomalidomide Krka contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU. The reference medicine for Pomalidomide Krka is Imnovid. For more information on generic medicines, see the question-and-answer document here.

How is Pomalidomide Krka used?

Treatment with Pomalidomide Krka must be started and supervised by a doctor experienced in treating multiple myeloma. The medicine can only be obtained with a prescription.

Pomalidomide Krka is available as capsules. It is taken daily in the first 2 weeks of 3-week treatment cycles, when given in combination with bortezomib and dexamethasone, and in the first 3 weeks of 4-week treatment cycles when given in combination with dexamethasone only.

Treatment with Pomalidomide Krka may need to be interrupted or stopped, or the dose may need to be reduced, if the disease gets worse or certain side effects occur. For more information about using Pomalidomide Krka, see the package leaflet or contact your doctor or pharmacist.

How does Pomalidomide Krka work?

The active substance in Pomalidomide Krka, pomalidomide, is an immunomodulating agent. This means that it affects the activity of the immune system (the body's natural defences). Pomalidomide works in a number of ways in multiple myeloma: it blocks the development of tumour cells, prevents the growth of blood vessels within tumours and also stimulates some specialised cells of the immune system to attack the tumour cells.

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How has Pomalidomide Krka 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, Imnovid, and do not need to be repeated for Pomalidomide Krka.

As for every medicine, the company provided studies on the quality of Pomalidomide Krka. The company also carried out a study 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 Pomalidomide Krka?

Because Pomalidomide Krka 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 Pomalidomide Krka authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pomalidomide Krka has been shown to have comparable quality and to be bioequivalent to Imnovid. Therefore, the Agency's view was that, as for Imnovid, the benefits of Pomalidomide Krka 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 Pomalidomide Krka?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pomalidomide Krka have been included in the summary of product characteristics and the package leaflet. Any additional measures in place for Imnovid, such as a patient card with key safety information, also apply to Pomalidomide Krka where appropriate.

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

Other information about Pomalidomide Krka

Pomalidomide Krka received a marketing authorisation valid throughout the EU on 24 July 2024.

Further information on Pomalidomide Krka can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/pomalidomide-krka.

Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 07-2024.