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Pomalidomide Teva (*pomalidomide*)

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

What is Pomalidomide Teva and what is it used for?

Pomalidomide Teva 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 prior 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 Teva contains the active substance pomalidomide and is a 'generic medicine'. This means that Pomalidomide Teva 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 Teva is Imnovid. For more information on generic medicines, see the question-and-answer document here.

How is Pomalidomide Teva used?

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

Pomalidomide Teva is available as capsules to be taken by mouth. When given in combination with bortezomib and dexamethasone, it is taken daily in the first 2 weeks of 3-week treatment cycles. When given with dexamethasone only, it is taken daily in the first 3 weeks of 4-week treatment cycles.

If the disease gets worse or certain side effects occur, treatment with Pomalidomide Teva may need to be interrupted or stopped, or the dose may need to be reduced.

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

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How does Pomalidomide Teva work?

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

How has Pomalidomide Teva been studied?

Studies on the benefits and risks of the active substance in the authorised use have already been carried out with the reference medicine, Imnovid, and do not need to be repeated for Pomalidomide Teva.

As for every medicine, the company provided studies on the quality of Pomalidomide Teva. 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 Teva?

Because Pomalidomide Teva 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 Teva authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Pomalidomide Teva 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 Teva 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 Teva?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Pomalidomide Teva 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 Teva where appropriate.

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

Other information about Pomalidomide Teva

Pomalidomide Teva received a marketing authorisation valid throughout the EU on 14 November 2024.

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

This overview was last updated in 11-2024.