EMA/48254/2024
EMEA/H/C/006195

# Pomalidomide Viatris (*pomalidomide*)

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

## What is Pomalidomide Viatris and what is it used for?

Pomalidomide Viatris 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 Viatris is a 'generic medicine'. This means that Pomalidomide Viatris 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 Viatris is Imnovid. For more information on generic medicines, see the question-and-answer document here.

Pomalidomide Viatris contains the active substance pomalidomide

## How is Pomalidomide Viatris used?

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

Pomalidomide Viatris is available as capsules (1, 2, 3 and 4 mg). It is taken 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. The recommended starting dose is 4 mg once a day, taken at the same time each day.

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

## How does Pomalidomide Viatris work?

The active substance in Pomalidomide Viatris, 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, similarly to other immunomodulating medicines such

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as lenalidomide and thalidomide: 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.

## How has Pomalidomide Viatris 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 Viatris.

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

Because Pomalidomide Viatris 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 Viatris authorised in the EU?

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

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

Any additional measures in place for reference medicine, such as a patient card with key safety information, also apply to Pomalidomide Viatris where appropriate.

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

## Other information about Pomalidomide Viatris

Pomalidomide Viatris received a marketing authorisation valid throughout the EU on 16 February 2024.

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

This overview was last updated in 02-2024.