LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pomalidomide Grindeks (pomalidomide)

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Summary Public Assessment Report

Pomalidomide Grindeks
pomalidomide

Capsule, hard, 1 mg, 2 mg, 3 mg, 4 mg

This is a summary of the public assessment report (PAR) for Pomalidomide Grindeks. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Pomalidomide Grindeks and what is it used for?

The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Imnovid, 1 mg, capsule, hard.

Pomalidomide Grindeks contains the active substance 'pomalidomide'. This medicine is related to thalidomide and belongs to a group of medicines which affect the immune system (the body's natural defences).

Pomalidomide Grindeks is used to treat adults with a type of cancer called 'multiple myeloma'.

Pomalidomide Grindeks is either used with:

- **two other medicines** - called 'bortezomib' (a type of chemotherapy medicine) and 'dexamethasone' (an anti-inflammatory medicine) in people who have had at least one other treatment - including lenalidomide.

Or

- **one other medicine** - called 'dexamethasone' in people whose myeloma has become worse, despite having at least two other treatments - including lenalidomide and bortezomib.

How does Pomalidomide Grindeks work?

Pomalidomide Grindeks works in a number of different ways:

- by stopping the myeloma cells developing
- by stimulating the immune system to attack the cancer cells
- by stopping the formation of blood vessels supplying the cancer cells.

<u>The benefit of using Pomalidomide Grindeks with bortezomib and dexamethasone</u>
When pomalidomide is used with bortezomib and dexamethasone, in people who have had at least one other treatment, it can stop multiple myeloma getting worse.
On average, pomalidomide when used with bortezomib and dexamethasone stopped multiple myeloma from coming back for up to 11 months - compared with 7 months for those patients who only used bortezomib and dexamethasone.

<u>The benefit of using Pomalidomide Grindeks with dexamethasone</u>
When pomalidomide is used with dexamethasone, in people who have had at least two other treatments, itcan stop multiple myeloma getting worse.
On average, pomalidomide when used with dexamethasone stopped multiple myeloma from coming back for up to 4 months - compared with 2 months for those patients who used only dexamethasone.

How is Pomalidomide Grindeks used?

The pharmaceutical form is capsule, hard for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Pomalidomide Grindeks have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Imnovid. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Pomalidomide Grindeks?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Pomalidomide Grindeks approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine. Therefore, the Swedish Medical Products Agency decided that, as for Imnovid, the benefits are greater than its risks and recommended that it can be approved for use.

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of Pomalidomide Grindeks?”

What measures are being taken to ensure the safe and effective use of Pomalidomide Grindeks?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

In addition, additional educational material will be provided to Healthcare Professional and patients.

Other information about Pomalidomide Grindeks

The full PAR for Pomalidomide Grindeks can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Pomalidomide Grindeks , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2024-12.