LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Pomalidomide Anabiosis (pomalidomide)

SE/H/2472/01-04/DC

Postadress/Postal address: P.O. Box 26, SE-751 03 Uppsala, SWEDEN
Besöksadress/Visiting address: Dag Hammarskjölds väg 42, Uppsala
Telefon/Phone: +46 (0)18 17 46 00 Fax: +46 (0)18 54 85 66
Internet: www.lakemedelsverket.se E-mail: registrator@lakemedelsverket.se

Summary Public Assessment Report

Pomalidomide Anabiosis
pomalidomide

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

This is a summary of the public assessment report (PAR) for Pomalidomide Anabiosis. 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 Anabiosis 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.

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

How does Pomalidomide Anabiosis work?

Sulabcote 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).

Multiple myeloma is a type of cancer which affects a certain type of white blood cell (called the 'plasma cell'). These cells grow out of control and accumulate in the bone marrow. This results in damage to the bones and kidneys.

Multiple myeloma generally cannot be cured. However, treatment can reduce the signs and symptoms of the disease, or make them disappear for a period of time. When this happens, it is called 'response'.

How is Pomalidomide Anabiosis used?

The pharmaceutical form is hard capsules 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 Anabiosis 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 in healthy volunteers. 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 Anabiosis?

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 Anabiosis 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 Anabiosis?"

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

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.

The MAH shall agree the details of a controlled access programme with the National Competent Authorities and must implement such programme nationally to ensure that:

Prior to prescribing (where appropriate, and in agreement with the National Competent Authority, dispensing) all healthcare professionals who intend to prescribe (and dispense) <Product name> are provided with an Educational Healthcare Professional's Kit containing the following:

- o Educational Healthcare Professional brochure
- o Educational brochures for patients
- o Patient cards
- o Risk awareness forms
- o Information on where to find latest Summary of Product Characteristics (SmPC)

The MAH shall implement a pregnancy prevention programme (PPP) in each Member State. Details of the PPP should be agreed with the National Competent Authorities in each Member State and put in place prior to the marketing of the medicinal product.

The MAH should agree the final text of the Educational Healthcare Professional's Kit with the National Competent Authority in each Member State prior to launch of the medicinal product and ensure that the materials contain the key elements as described below.

The MAH should agree on the implementation of the controlled access programme in each Member State.

Other information about Pomalidomide Anabiosis

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

This summary was last updated in 2024-12.