LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Imolopera
(loperamide hydrochloride)

SE/H/2287/01/MR

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

Imolopera
loperamide hydrochloride

Tablet, 2 mg

This is a summary of the public assessment report (PAR) for Imolopera. 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 Imolopera 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 Imodium.

Imolopera is primarily used in the treatment of acute diarrhoea. It can also be prescribed by doctors for the treatment of chronic diarrhoea, in ostomy after gastrointestinal operations and to prevent faecal incontinence.

How does Imolopera work?

Imolopera normalizes bowel movements, neutralizes fluid loss and increases the ability to hold stool.

How is Imolopera used?

The pharmaceutical form is tablet 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.
A prescription might be needed for this medicine in Sweden.

What benefits of Imolopera have been shown in studies?

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

What are the possible side effects from Imolopera?
Because Imolopera 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 Imolopera 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, Imodium. Therefore, the Swedish Medical Products Agency decided that, as for Imodium, the benefits are greater than its risks and recommended that it can be approved for use.

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

A risk management plan has been developed to ensure that Imolopera 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.

Other information about Imolopera

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

This summary was last updated in 2023-03.