COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Loperamide HCl Sanias 2 mg, hard capsules

(loperamide)

NL/H/4046/001/DC

Date: 8 November 2018

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Active substance: loperamide

This is a summary of the public assessment report (PAR) for Loperamide HCl Sanias 2 mg, hard capsules. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Loperamide HCl Sanias.

For practical information about using this medicine, patients should read the package leaflet or contact their doctor or pharmacist.

What is Loperamide HCl Sanias and what is it used for?
Loperamide HCl Sanias is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Imodium.

This medicine is used for the treatment of sudden short-lived (acute) attacks of diarrhoea in adults and children over 12 years of age. This medicine must not be used for more than 2 days without medical advice and surveillance.

How does this medicine work?
This medicine contains loperamide which helps to stop diarrhoea by making the stools more solid and less frequent.

How is this medicine used?
The pharmaceutical form of Loperamide HCl Sanias is a hard capsules and the route of administration is oral. The capsules should be swallowed whole with a drink of water.

The medicine can be obtained without a prescription.

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

How has this medicine been studied?
Because Loperamide HCl Sanias 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 of this medicine?
Because Loperamide HCl Sanias is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent/be comparable to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for reference medicine, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 for Loperamide HCl Sanias, 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 this medicine
In the Netherlands, the marketing authorisation for Loperamide HCl Sanias 2 mg, hard capsules was granted on 27 August 2018.

The full PAR for this medicine can be found on the website http://mri.cts-mrp.eu/Human/. For more information about treatment with Loperamide HCl Sanias 2 mg, hard capsules, read the package leaflet (http://mri.cts-mrp.eu/Human/Product/Details/53671) or contact your doctor or pharmacist.

This summary was last updated in November 2018.