COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Summary Public Assessment Report

Generics

Loperamide HCL Tenshi 2 mg, oral lyophilisate (loperamide)

NL/H/4900/001/DC

Date: 8 November 2021

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Loperamide HCL Tenshi 2 mg, oral lyophilisate
Active substance: loperamide

This is a summary of the public assessment report (PAR) for Loperamide HCL Tenshi. 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 Tenshi.

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

What is Loperamide HCL Tenshi and what is it used for?
Loperamide HCL Tenshi is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Imodium Instant smelttablet 2 mg, orodispersible tablets.

This medicine is used for the treatment of sudden short-lived (acute) attacks of diarrhoea in adults and adolescents over 12 years of age.

How does this medicine work?
Loperamide HCL Tenshi contains a substance 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 Tenshi is a dissolving tablet (lyophilisate) and the route of administration is by mouth (oral).
It should be placed on the tongue, where it dissolves and can be swallowed with the saliva. No liquid intake is needed.

The medicine can be obtained without a prescription.

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

How has this medicine been studied?
Because Loperamide HCL Tenshi is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Imodium Instant. 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 Tenshi 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 to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Imodium Instant, 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 Tenshi, 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 Tenshi was granted on 26 August 2021.

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 Tenshi, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in November 2021.