Summary Public Assessment Report

Generics

Pantoprazole Olikla
Pantoprazole sodium sesquihydrate

SK/H/0301/001/DC

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Pantoprazole sodium sesquihydrate, powder for solution for injection. Each vial of powder for solution for injection contains 40 mg pantoprazole (as pantoprazole sodium sesquihydrate 44.94 mg).
This is a summary of the public assessment report (PAR) for Pantoprazole Olikla. It explains how Pantoprazole Olikla 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 Pantoprazole Olikla.

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

What is Pantoprazole Olikla and what is it used for?

Pantoprazole Olikla is a 'generic medicine'. This means that Pantoprazole Olikla is similar to a 'reference medicine' already authorised in the European Union (EU) called Controloc.
Pantoprazole Olikla is used in the treatment of adults with:

- Reflux oesophagitis
- Stomach and duodenal ulcers
- Zollinger–Ellison Syndrome and other conditions producing too much acid in the stomach

How does Pantoprazole Olikla work?

Pantoprazole Olikla contains the active substance pantoprazole (as sodium sesquihydrate). Pantoprazole is a selective "proton pump inhibitor", a medicine which reduces the amount of acid produced in the stomach. It is used for treating acid-related diseases of the stomach and intestine.

How is Pantoprazole Olikla used?

The pharmaceutical form of Pantoprazole Olikla is powder for solution for injection and the route of administration is intravenous.

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

The intravenous administration of Pantoprazole Olikla is recommended only if oral application is not appropriate. Therefore as soon as oral therapy is possible, treatment with

intravenous pantoprazole should be discontinued and 40 mg oral pantoprazole should be administered instead.

The medicine can only be obtained with a prescription.

What benefits of Pantoprazole Olikla have been shown in studies?

No additional studies were needed as Pantoprazole Olikla is a generic medicine that is given by intravenous injection and contains the same active substance as the reference medicine, reference medicine called Controloc.

What are the possible side effects of Pantoprazole Olikla?

Because Pantoprazole Olikla 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 restrictions, see the package leaflet.

Why is Pantoprazole Olikla approved?

It was concluded that, in accordance with EU requirements, Pantoprazole Olikla has been shown to have comparable quality and to be bioequivalent to Controloc. Therefore, the State Institute for Drug Control decided that, as for reference medicine called Controloc, 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 Pantoprazole Olikla?

A risk management plan has been developed to ensure that Pantoprazole Olikla 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 Pantoprazole Olikla, 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 Pantoprazole Olikla

The marketing authorisation for Pantoprazole Olikla was granted on 25.04.2024.

The full PAR for Pantoprazole Olikla can be found on the website. For more information about treatment with Pantoprazole Olikla, read the package leaflet (link) or contact your doctor or pharmacist.

This summary was last updated in 09-2024.