

Summary Public Assessment Report

Esomeprazol Hospira (esomeprazole)

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(esomeprazole)

40mg, powder for solution for infusion/injection

This is a summary of the public assessment report (PAR) for Esomeprazol Hospira. It explains how Esomeprazol Hospira 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 Esomeprazol Hospira.

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

What is Esomeprazol Hospira and what is it used for?

Esomeprazol Hospira is a ‘generic medicine’. This means that Esomeprazol Hospira is similar to a ‘reference medicine’ already authorised in the European Union (EU) called Nexium.

Esomeprazole is used for the short-term treatment of certain conditions, when you are unable to have treatment by mouth. It is used to treat:

- ‘Gastro-oesophageal reflux disease’ (GORD) in adults, adolescents and children. This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.
- Stomach ulcers in adults caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazole can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Prevention of rebleeding in adults following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

How does Esomeprazol Hospira work?

Esomeprazole Hospira contains a medicine called esomeprazole. This belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

How is Esomeprazol Hospira used?

The pharmaceutical form of Esomeprazol Hospira is powder for solution for infusion/injection for intravenous injections/infusions.

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.

What benefits of Esomeprazol Hospira have been shown in studies?

No additional studies were needed as Esomeprazol Hospira is a generic medicine that is given by infusion/intravenous injection and contains the same active substance as the reference medicine, Nexium.

What are the possible side effects of Esomeprazol Hospira?

Because Esomeprazol Hospira 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 restrictions, see the package leaflet.

Why is Esomeprazol Hospira approved?

It was concluded that, in accordance with EU requirements, Esomeprazol Hospira has been shown to have comparable quality and to be similar to the reference medicine Nexium. Therefore, the Medical Products Agency in Sweden decided that, as for Nexium, 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 Esomeprazol Hospira?

A risk management plan has been developed to ensure that Esomeprazol Hospira 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 Esomeprazol Hospira, 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 Esomeprazol Hospira

The marketing authorisation for Esomeprazol Hospira was granted on 2014-08-28 in Sweden.

The full PAR for Esomeprazol Hospira can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Esomeprazol Hospira, please read the [package leaflet](#) or contact your doctor or pharmacist.

This summary was last updated in 2014-08