

# **Summary Public Assessment Report**

## **Esomeprazol Oresund Pharma (esomeprazole sodium)**

**SE/H/2373/01/DC**

# Summary Public Assessment Report

Esomeprazol Oresund Pharma  
esomeprazole sodium

Powder for solution for injection/infusion, 40 mg

This is a summary of the public assessment report (PAR) for Esomeprazol Oresund Pharma. 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 Esomeprazol Oresund Pharma 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 Nexium.

The product is used to treat the following conditions:

### Adults

- 'Gastroesophageal reflux disease' (GERD). 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 caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Esomeprazol Oresund Pharma can also be used to stop stomach ulcers from forming if you are taking NSAIDs.
- Prevention of rebleeding following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers.

### Children and adolescents aged 1-18 years

- 'Gastroesophageal reflux disease' (GERD). 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.

## How does Esomeprazol Oresund Pharma work?

The product 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 Oresund Pharma used?

The pharmaceutical form is powder for solution for injection/infusion. This is made into a solution before it is given to you as an injection or infusion into a vein.

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 in Sweden.

### **What benefits of Esomeprazol Oresund Pharma have been shown in studies?**

No additional studies were needed as the product 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 from Esomeprazol Oresund Pharma?**

Because the product 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 Esomeprazol Oresund Pharma 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. Therefore, the Swedish Medical Products Agency 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 Oresund Pharma?**

A risk management plan has been developed to ensure that the product 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 Esomeprazol Oresund Pharma**

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

This summary was last updated in 2024-02-07.