LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Nexizol
(esomeprazole magnesium)

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Summary Public Assessment Report

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esomeprazole magnesium

Gastro-resistant granules for oral suspension in sachet, 10 mg

This is a summary of the public assessment report (PAR) for Nexizol. 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 Nexizol 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:

Children over 1 year of age
The product is used to treat a condition called "gastroesophageal reflux disease" (GERD).
- This is where acid from the stomach escapes into the gullet (esophagus) causing pain, inflammation and heartburn. Heartburn is a burning feeling rising from the stomach or lower chest up towards the neck.
- In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

Children over 4 years of age
- Ulcers which are infected with bacteria called 'Helicobacter pylori'. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

How does Nexizol work?

The product contains a substance called esomeprazole. This belongs to a group of medicines called proton pump inhibitors. These work by reducing the amount of acid that your stomach produces.

How is Nexizol used?

The pharmaceutical form is gastro-resistant granules for oral suspension in sachet for oral use.

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 Nexizol have been shown in studies?

Because the product is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Nexium. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Nexizol?

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 Nexizol 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 Nexizol?

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 Nexizol

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

This summary was last updated in 2023-09.