

Summary Public Assessment Report

Omeprazole STADA (omeprazole)

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omeprazole

Gastro-resistant capsule, hard, 10 mg, 20 mg, 40 mg

This is a summary of the public assessment report (PAR) for Omeprazole STADA. 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 Omeprazole STADA and what is it used for?

The product is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as Gastro-resistant capsule, hard compared to the reference medicine which is Gastro-resistant tablet.

The reference medicine for the product is Losec.

The product is used in the treatment of:

In adults:

- 'Gastro-esophageal 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.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). <invented name> can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children:

Children over 1 year of age and ≥ 10 kg

- 'Gastro-esophageal 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.
- 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 and adolescents 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 Omeprazole STADA work?

It belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

How is Omeprazole STADA used?

The pharmaceutical form is Gastro-resistant capsule, hard 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 Omeprazole STADA have been shown in studies?

Because the product is a hybrid application of Losec, clinical studies have been provided for Omeprazole STADA to show efficacy for the difference of Omeprazole STADA from the reference product Losec.

What are the possible side effects from Omeprazole STADA?

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 Omeprazole STADA 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 Losec, 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 Omeprazole STADA?

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 Omeprazole STADA

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

This summary was last updated in 2023-09.

