

Summary Public Assessment Report

Omeprazol Medical Valley (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 Omeprazol Medical Valley. 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 Omeprazol Medical Valley 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 medical product which is available as gastro-resistant tablet.

The reference medicine for the product is Losec.

The product is used in the treatment of:

Adults:

- Gastro-oesophageal reflux disease (GORD). 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). Omeprazol Medical Valley 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).

Children:

Children over 1 year of age and ≥ 10 kg

- Gastro-oesophageal reflux disease (GORD). 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 Omeprazol Medical Valley work?

Omeprazol Medical Valley contains the active substance omeprazole. 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 Omeprazol Medical Valley 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 Omeprazol Medical Valley have been shown in studies?

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

What are the possible side effects from Omeprazol Medical Valley?

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 Omeprazol Medical Valley 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.

Om villkor enligt art. 21a, art. 22

The product has been authorised under "exceptional circumstances". This means that it has not been possible to obtain complete information about the product due to *<insert reason based on rarity/scientific/ethical grounds (see also PAR)>*. Every year, the national Agencies will review any new information that becomes available, and this summary will be updated as necessary.>

The product has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below "What measures are being taken to ensure the safe and effective use of Omeprazol Medical Valley?">

What measures are being taken to ensure the safe and effective use of Omeprazol Medical Valley?

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 Omeprazol Medical Valley

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

This summary was last updated in 2023-05.