Summary Public Assessment Report

Generics

Prenome 10 mg, 20 mg and 40 mg gastro-resistant capsules, hard

(omeprazole)

NL/H/2940/001-003/DC

Date: 11 February 2015

Summary Public Assessment Report

Generics

Prenome 10 mg, 20 mg and 40 mg gastro-resistant capsules, hard
Active substance: omeprazole

This is a summary of the public assessment report (PAR) for Prenome 10 mg, 20 mg and 40 mg gastro-resistant capsules, hard. It explains how this medicine 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 Prenome.

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

What is Prenome and what is it used for?
Prenome is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Losec 10 mg, 20 mg and 40 mg gastro-resistant capsules.

This medicine reduces the amount of acid in the stomach.
It can be used to treat the following conditions:

Adults
- 'Gastro-oesophageal reflux disease' (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects the throat to the 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'. In patients who have this condition, the 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). This medicine can also be used to stop stomach ulcers from forming while taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

Children aged over 1 year and ≥ 10 kg
- 'Gastro-esophageal reflux disease' (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects the throat to the 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 aged over 4 years and adolescents
- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. When a child has this condition, the doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

How does this medicine work?
The active substance omeprazole is a proton pump inhibitor. It works by blocking 'proton pumps', proteins found in specialised cells in the stomach lining, which pump acid into the stomach. By blocking the pumps, omeprazole reduces the amount of acid.

How is this medicine used?
The pharmaceutical form of Prenome is a hard gastro-resistant capsule and the route of administration is oral. The medicine can only be obtained with a prescription.
It is recommended to take the capsules in the morning, with food or on an empty stomach. The capsules should be swallowed whole with half a glass of water. They must not be chewed or crushed.

A doctor determines how many tablets should be taken and for how long. The correct dose depends on the condition and age of the patient.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

How has this medicine been studied?
Because Prenome is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Losec. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of this medicine?
Because Prenome is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be bioequivalent to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Losec, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Prenome, 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 this medicine
In the Netherlands, the marketing authorisation for Prenome 10 mg, 20 mg and 40 mg gastro-resistant capsules, hard was granted on 18 July 2014.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human.
For more information about treatment with Prenome gastro-resistant capsules, read the package leaflet (http://mri.medagencies.org/download/NL_H_2940_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in February 2015.