LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Espikur
(^{13}C-urea)

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Summary Public Assessment Report

Espikur

(^{13}C-urea)

Tablet; 50 mg

This is a summary of the public assessment report (PAR) for Espikur. It explains how Espikur 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 Espikur.

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

What is Espikur and what is it used for?

Espikur is a medicine for diagnostic use only. Espikur is a breath test that will show if the patient is infected by the bacterium *Helicobacter pylori* in the stomach.

How does Espikur work?

Espikur is a breath test for diagnostic use only. After taking the tablet, the breath test will show if the patient is infected by the bacterium *Helicobacter pylori* in the stomach and whether the infection has been treated successfully.

How is Espikur used?

The pharmaceutical form of Espikur is tablet 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.

What benefits of Espikur have been shown in studies?

The company provided its own data on efficacy and safety studies. These studies have shown that Espikur is effective for *In vivo* diagnosis of primary or remaining gastroduodenal *Helicobacter pylori* infection in adults. This medicinal product is for diagnostic use only.

What are the possible side effects of Espikur?

For the full list of all side effects reported with Espikur, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Espikur approved?

It was noted that the performance of Espikur for *In vivo* diagnosis of primary or remaining gastroduodenal *Helicobacter pylori* infection in adults is not inferior in comparison to already approved products as well as reference diagnostic methods. The Medical Products Agency in Sweden decided that Espikur's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Espikur?

A risk management plan has been developed to ensure that Espikur 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 Espikur, 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 Espikur

The marketing authorisation for Espikur was granted on 2019-06-10 in Sweden.

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

This summary was last updated in 2020-01.