

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)**HELICOBACTER TEST INFAI****EPAR summary for the public**

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.

If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Helicobacter Test INFAI?

Helicobacter Test INFAI is a diagnostic test. It is available as a jar containing a powder to be made up into a solution for drinking. The powder is the active substance ^{13}C -urea (45 mg for children or 75 mg for adults).

What is Helicobacter Test INFAI used for?

Helicobacter Test INFAI is used to diagnose *Helicobacter pylori* infection in the stomach and duodenum (the part of the gut just below the stomach). *H. pylori* is a bacterium that is a factor in diseases such as dyspepsia (heartburn, bloating and nausea), gastritis (inflammation of the stomach), and peptic ulcer disease (ulcers in the stomach or the duodenum).

Helicobacter Test INFAI can be used to test adults, adolescents who are likely to have peptic ulcer disease, and children aged three to 11 years. It can only be used in children when invasive tests (taking a sample from the stomach using a probe) cannot be carried out or have given questionable results, or to check that *H. pylori* has been eliminated after a specific treatment to clear up the infection.

The medicine can only be obtained with a prescription.

How is Helicobacter Test INFAI used?

Helicobacter Test INFAI is a breath test: breath samples are collected, which are then sent out for analysis to a specialised laboratory.

To carry out the test, the patient must collect four samples, two before taking Helicobacter Test INFAI and two thereafter. The patient should not eat for at least six hours, preferably overnight, before taking the test. Firstly, the patient collects two breath samples, using the tubes or bags supplied with Helicobacter Test INFAI. The patient then takes a 'test meal' (either 200 ml of pure orange juice or 1 g of citric acid dissolved in 200 ml water), followed by the solution of Helicobacter Test INFAI dissolved in water. Finally, 30 minutes after drinking the solution, the patient collects a further two breath samples. In children aged three to 11 years, the 'test meal' should be 100 ml of pure orange juice. For full information on how the test is carried out, see the Package Leaflet.

How does Helicobacter Test INFAI work?

The active substance in Helicobacter Test INFAI, ^{13}C -urea, is the natural chemical urea that has been labelled with carbon-13 (^{13}C). This means that it contains ^{13}C , a rare form of the carbon atom, instead of carbon-12 (^{12}C), the form that is the most common in nature.

H. pylori contain enzymes called ureases that make it able to break down urea into carbon dioxide, which is then removed in the breath. When the patient takes Helicobacter Test INFAI, the ¹³C-urea contained in the test is broken down by *H. Pylori* into carbon dioxide that also contains ¹³C. This labelled carbon dioxide can be measured by specialised laboratories using a technique called mass spectrometry. If there is labelled carbon dioxide in the breath sample after 30 minutes (a positive test), this means that the patient is infected with *H. pylori*. If there is no labelled carbon dioxide in the breath, this means there are no bacteria in the stomach or duodenum.

How has Helicobacter Test INFAI been studied?

Helicobacter Test INFAI has been tested in four studies in adult patients involving a total of 561 patients and one study in 335 children and adolescents. All received 75 mg of ¹³C-urea, except 204 children under the age of 11 who received 45 mg. One of the studies in adults was carried out in patients after they had received antibiotics to treat their infection. In all studies, patients underwent an endoscopy and histology (when a probe is inserted in the stomach to take a sample and the sample is then analysed) as well as a breath test with Helicobacter Test INFAI, and the results of the two tests were compared.

What benefit has Helicobacter Test INFAI shown during the studies?

In all studies, the results of the test done using Helicobacter Test INFAI agreed with the results obtained with the endoscopy and histology in over 95% of cases.

What is the risk associated with Helicobacter Test INFAI?

There are no known side effects of the test. However, if the patient vomits during the test, the test will need to be done again, but not until at least the following day.

Helicobacter Test INFAI should not be used in patients who have, or may have gastric (stomach) infection or atrophic gastritis (stomach inflammation that causes the breakdown of the stomach lining), as these might interfere with the breath test.

Why has Helicobacter Test INFAI been approved?

The Committee for Medicinal products for Human Use (CHMP) decided that Helicobacter Test INFAI's benefits are greater than its risks for the *in vivo* diagnosis of gastroduodenal *H. pylori* infection in adults, adolescents who are likely to have peptic ulcer disease, and children aged three to 11 years for the evaluation of the success of eradication treatment, or when invasive tests cannot be performed, or when there are discordant results arising from invasive tests. The Committee recommended that Helicobacter Test INFAI be given marketing authorisation.

Other information about Helicobacter Test INFAI:

The European Commission granted a marketing authorisation valid throughout the European Union for Helicobacter Test INFAI to INFAI, Institut für biomedizinische Analytik & NMR-Imaging GmbH on 14 August 1997. The marketing authorisation was renewed on 14 August 2002 and 14 August 2007.

The full EPAR for Helicobacter Test INFAI is available [here](#).

This summary was last updated in 09-2007.