European Medicines Agency

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PYLOBACTELL

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 Pylobactell?

Pylobactell is a diagnostic test. It is available as a kit that includes a white soluble tablet containing 100 mg of the active substance ^{13}C-urea.

What is Pylobactell used for?

Pylobactell is used to diagnose *Helicobacter pylori* (*H.* 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).
The medicine can only be obtained with a prescription.

How is Pylobactell used?

Pylobactell is a breath test: breath samples are collected in the tubes provided in the kit. These samples are then sent for analysis at a specialised laboratory.
To carry out the test, the patient must collect six breath samples, three before taking the Pylobactell tablet and three after taking it. The patient should fast for four hours before the test so that it is done on an empty stomach. If the patient has eaten a heavy meal then they should fast for six hours before the test.
First, the patient takes a 'test meal' (such as 200 ml of pure undiluted orange juice). Five minutes later, the patient collects three breath samples. After a further five minutes, the patient takes the Pylobactell tablet dissolved in water. Finally, 30 minutes later (40 minutes after the test meal), the patient collects a further three breath samples. For full information on how the test is carried out, see the Package Leaflet.
Pylobactell is not recommended for use in patients below 18 years of age because there is insufficient information on its effectiveness in this group.

How does Pylobactell work?

The active substance in Pylobactell, ^{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 produces enzymes called ureases that break down urea into ammonia and carbon dioxide. The carbon dioxide is then removed from the body in the breath. If the patient has , the ^{13}C-urea

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contained in the Pylobactell tablet is broken down and the carbon dioxide in the breath also contains ^{13}C. This ^{13}C-labelled carbon dioxide can be measured by specialised laboratories using a technique called mass spectrometry. If there is an increased level of labelled carbon dioxide in the breath sample after 30 minutes (a positive test), the patient may have *H. pylori* in the stomach or duodenum. If there is no increased level of labelled carbon dioxide in the breath, the patient might not have *H. pylori* in the stomach or duodenum.

How has Pylobactell been studied?
The data to support the use of Pylobactell comes from two main studies of the use of antibiotics to treat *H. pylori* infection, where it was used as a test. A total of 366 patients underwent both a Pylobactell test and a standard biopsy test (where a sample from the stomach is analysed to see if it is infected). The results obtained were compared to see if they agreed.

What benefit has Pylobactell shown during the studies?
Pylobactell was more than 95% sensitive in detecting infection with *H. pylori*.

What is the risk associated with Pylobactell?
There are no known side effects of the test.
Pylobactell should not be used in people who may be hypersensitive (allergic) to ^{13}C-urea or any of the other ingredients in the tablet. Pylobactell should not be used in patients who have, or may have gastric (stomach) infection, which might interfere with the breath test.

Why has Pylobactell been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Pylobactell's benefits are greater than its risks for the *in vivo* diagnosis of gastroduodenal *H. pylori* infection. The Committee recommended that Pylobactell be given marketing authorisation.

Other information about Pylobactell:
The European Commission granted a marketing authorisation valid throughout the European Union for Pylobactell on 7 May 1998. The marketing authorisation was renewed on 7 May 2003 and on 7 May 2008. The marketing authorisation holder is Torbet Laboratories Limited.

The full EPAR for Pylobactell is available here.

This summary was last updated in 06-2008.