

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What the Pylobactell tablet contains

- The **active** substance is ^{13}C -urea. Each tablet contains 100 mg of ^{13}C -urea.

- The **other** ingredients are povidone (E1201), microcrystalline cellulose (E460i), colloidal anhydrous silica and sodium benzoate (E211).

Each Pylobactell Breath Test kit contains:

- 1 Sachet containing 1 tablet.
- 6 glass tubes, 3 with white caps and 3 with red caps.
- 30 ml glass mixing tube with cap.
- 2 straws.
- Package Leaflet (this leaflet).
- Analysis Request Form.
- Security Label and 3 additional bar code labels.

The contents of this kit are sufficient for a single test. If you need to repeat the test, a new kit will be required and it should not be carried out until the following day.

Marketing Authorisation Holder

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Manufacturer

J L Bragg Limited,
33-34 Boss Hall Road, Ipswich,
Suffolk, IP1 5BN, United Kingdom.

For any information about this medicine, please contact the Marketing Authorisation Holder:

This leaflet was last revised in 10/2015

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

Analysis of samples and testing specification

The accuracy and precision of the test depends heavily on the quality of the analysis and therefore only laboratories having appropriate certification are considered qualified to analyse the breath samples.

Satisfactory specificity and sensitivity have been demonstrated in clinical studies where breath was analysed using isotope ratio mass spectrometry (IRMS).

Breath samples collected during a test must remain in the original containers before analysis by IRMS.

IRMS instruments may be of continuous flow or dual inlet configuration.

A multi-position autosampler and bar code reader should be used to allow samples to be tracked throughout the analysis.

IRMS source parameters and tuning must be optimised daily.

Instruments must be linear over a wide range of CO_2 concentrations, typically 1.0 - 6.0%. This should be checked routinely.

Internal analytical precision must be less than + 0.3 ‰ $\delta^{13}\text{C}$ for 20 replicate analyses of the same reference gas sample and remain within 3SD's of the mean for breath analyses.

Transfer of the breath sample through the analytical system must be accomplished without isotope fractionation.

The IRMS must possess a triple collector to allow the simultaneous detection of the ions at mass/charge ratio 44, 45 and 46 to allow for fluctuations in the oxygen isotope content.

There must be provision for correction of instrumental drift during an analysis.

Reference gases must be standardised against an appropriate international standard to allow inter-laboratory comparison of results.

Alternatively, any other suitably-validated method may be used, carried out by any objectively qualified laboratory.

Explanation of results:

$\delta^{13}\text{C}$:
Difference in parts per thousand (‰) with respect to an accepted international standard

Excess $\delta^{13}\text{C}$:
Difference between pre- and post-urea sample measurements

H. pylori status:
< 3.5 excess $\delta^{13}\text{C}$ = Negative
≥ 3.5 excess $\delta^{13}\text{C}$ = Positive

Pylobactell[®]

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pylobactell 100mg soluble tablet ^{13}C -Urea

Read all of this leaflet carefully before you start using this medicine, because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Pylobactell is and what it is used for
2. What you need to know before you use Pylobactell
3. How to use Pylobactell
4. Possible side effects
5. How to store Pylobactell
6. Contents of the pack and other information



Torbet Laboratories Limited, Unit 1 Chestnut Drive, Wymondham, Norfolk, NR18 9SB, United Kingdom

1. WHAT PYLOBACTELL IS AND WHAT IT IS USED FOR

Pylobactell is a breath test for determining the presence of the bacterium, *Helicobacter pylori* (*H. pylori*) in the gut (stomach and adjacent bowel) which may be the reason for your stomach (gastric) condition.

Your doctor has recommended that you have a ¹³C-Urea breath test, for one of the following reasons:

- Your doctor wants to confirm whether you are suffering from *H. pylori* infection to help diagnose your condition.
- You have already been diagnosed with *H. pylori* and have been taking medication aimed to clear up the infection. Your doctor now wants to find out if the treatment has worked.

This medicine is for diagnostic use only.

How does the test work?

All foods contain a substance called carbon 13 (¹³C), in varying amounts. This ¹³C can be detected in the carbon dioxide that you breathe out of your lungs. The actual amount of ¹³C in the breath will depend on the type of food that you have eaten.

You will be asked to drink a "test meal". This will help keep the test ¹³C-urea solution in your stomach.

Following the meal, 3 samples of your breath will be taken. These samples will be analysed to measure the normal amount of ¹³C in the carbon dioxide in your breath.

You will then drink the Pylobactell ¹³C-urea solution. If *H. pylori* is present and active in your stomach, these bacteria will break down the ¹³C-urea and this is detected in the carbon dioxide in your breath.

A further 3 samples of your breath will then be taken 30 minutes later.

The amount of ¹³C in these samples will be compared to your normal level. If there is a significant increase in the amount of ¹³C, this will let your doctor know that active *H. pylori* is present.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE PYLOBACTELL

DO NOT use Pylobactell if you:

- are **allergic** to ¹³C-urea or to any of the other ingredients in the tablets (listed in Section 6).
- suffer from any **medical condition** that you think may affect, or be affected by, the test.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Pylobactell if:

- **part of your stomach has been removed** (partial gastrectomy) as the reliability of the test has not been proven in these patients
- you have or suspect you have a **gastric infection**
- you have **long term stomach problems** (atrophic gastritis) as the breath test may give the wrong result and other tests may be required to confirm the presence of *H. pylori*.
- **fasting** (not taking food) may have medical implications for you
- you are **under 18** years.

Other medicines and Pylobactell

Please tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not take the test if:

- **You have taken antibiotics or medication to treat *Helicobacter pylori* within the last 28 days**
- **You have taken proton pump inhibitors in the last 14 days**
- **You have taken H2 antagonists or antacids on the same day of the test.**

Do not stop taking medication without the advice of your doctor.

Taking Pylobactell with food and drink

You should fast for at least 4 hours before the test so that the test is taken on an empty stomach. If you have eaten a heavy meal it will be necessary to fast for six hours before the test.

You can drink water during the fasting period.

If fasting is a problem e.g. for diabetic patients, please tell your doctor, pharmacist or nurse.

Pregnancy and breast-feeding

Pylobactell can be used during pregnancy and breast-feeding.

Driving and using machines

This test should not affect your ability to drive or use machines.

3. HOW TO USE PYLOBACTELL

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The test will take about 45 minutes. A supply of drinking water will be needed.

It is recommended that the breath test is performed while you are in a seated position.

You must not smoke before or during the test.

The test procedure involves the following steps: (A brief form of these instructions is included on the back of the Analysis Request Form).

1. **Fasting:** You should fast for 4 hours before taking the test (See Section 2 *Taking Pylobactell with food and drink*).

2. **Test Meal:** Drink the recommended test meal. This is not included in this kit but may have been supplied separately. If no test meal has been supplied, the most suitable test meal is 200 ml of pure undiluted orange juice. If you cannot take the recommended test meal, an alternative test meal should be taken. Your doctor will advise you.

3. **Wait 5 minutes**

4. **Pre-test Breath Samples** (3 White Capped Tubes)

- Remove the cap from the tube.
- Breathe out through your mouth, using a straw, into the sample tube.

- Gradually remove the straw from the tube as you breathe out.
- Immediately replace the cap.
- Repeat with remaining white capped tubes.

It is not necessary to blow hard into the tubes, just breathe normally and cap them quickly. **Try to avoid getting saliva in the tubes.**

5. Preparing the ¹³Carbon-urea solution

Open the tablet sachet and empty the tablet into the mixer vial.

Add water to the mark on the vial and replace the cap.

Gently shake the vial to dissolve the tablet.

Drink the solution. Note the time upon drinking.

Fill the vial to the mark again with water and drink.

6. **Wait 30 minutes** from the time of drinking the Pylobactell ¹³C-urea solution. Do not smoke, eat or drink during this time. This is important for the proper functioning of the test.

7. Post-test Breath Samples

 (3 Red Capped Tubes)

Using the red-capped tubes, take samples of your breath as before (see step 4).

8. Analysis Request Form

Fill out the analysis request form with patient details on the left hand side of the form and the doctor's name and address on the right hand side.

9. Test is now complete

Put your breath samples and the completed Analysis Request Form back into the carton and send to the address supplied by your doctor. Your doctor will tell you when the results of your test will be available and who to contact for these results.

Dispose of the empty sachet, mixing vial and straws as normal waste, but keep this leaflet for reference.

If a repeat test is required, it should not be carried out until the following day.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

No side effects to Pylobactell have been reported. ¹³C and urea are harmless naturally occurring substances which are found in your body.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme
Website:
www.mhra.gov.uk/yellowcard

Ireland

IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail:
imbpharmacovigilance@imb.ie

5. HOW TO STORE PYLOBACTELL

Keep out of the sight and reach of children

Do not store the kit above 25°C. The tablet must be taken when dissolved.

Do not use Pylobactell after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.