

# Helicobacter Test

## *INFAI*<sup>®</sup>

**Package leaflet: Information for the user**

**Helicobacter Test *INFAI***  
**75 mg powder for oral solution**  
<sup>13</sup>C-urea

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### **What is in this leaflet:**

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

## 1. What Helicobacter Test *INFAI* is and what it is used for

Helicobacter Test *INFAI* is for diagnostic use only. It is a breath test for adolescents from the age of 12 and adults to **determine the presence of bacterium *Helicobacter pylori* in the stomach.**

### Why do you need to take the Helicobacter Test *INFAI*?

You may have a gastric infection caused by a bacterium called *Helicobacter pylori*. Your doctor has recommended that you have a Helicobacter Test *INFAI* for one of the following reasons:

- > Your doctor wants to confirm whether you are suffering from *Helicobacter pylori* infection to help diagnose your condition.
- > You have already been determined as being infected with *Helicobacter pylori* and have been taking medication aimed to clear up the infection. Your doctor now wishes to find out if the treatment has been successful.

### How does the test work?

All foods contain a substance called carbon-13 (<sup>13</sup>C). This carbon-13 can be detected in the carbon dioxide you breathe out of your lungs. The actual amount of carbon-13 in the breath will depend on the kind of food that you have eaten.

You will be asked to drink the “test meal”. Following the meal, samples of your breath will be taken. See “Special instructions for use”. These samples will be analysed to measure the “normal” amount of carbon-13 content in the carbon dioxide in your breath.

You will then be asked to drink a solution of carbon-13-urea. Further samples of your breath will then be taken 30 minutes later and the amount of carbon-13 in the samples measured as before. The results will be compared and a significant increase in the amount of

carbon-13 in the second set of samples will suggest to your doctor that *Helicobacter pylori* is present.

## 2. What you need to know before you take Helicobacter Test *INFAI*

### Do not take Helicobacter Test *INFAI*

- if you have or suspect that you have a **stomach infection** or a certain **inflammation of the stomach lining** (atrophic gastritis).

This inflammation of the stomach lining may cause incorrect positive results of your breath test. Further investigations may be required to confirm the presence of *Helicobacter pylori*.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Helicobacter Test *INFAI* if you have any condition that can affect or be affected by the test.

Even if the result of Helicobacter Test *INFAI* is positive, further tests might be necessary before a treatment of a *Helicobacter pylori* infection may be started. These are required to check for the presence of any other complications, such as:

- stomach ulcer
- inflammation of the stomach lining caused by immune system
- tumours

There is insufficient data on the reliability of the Helicobacter Test *INFAI* for recommending its use in patients with removal of parts of the stomach.

If the patient vomits during the test procedure, repetition of the test is necessary. This should be done in fasted condition and not before the following day.

### Other medicines and Helicobacter Test *INFAI*

Helicobacter Test *INFAI* is influenced by medicines influencing

- *Helicobacter pylori* (see section 3, second paragraph under “Method of use”)
- the enzyme urease, which stimulate the reduction of urea

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not expected that performing the breath test during pregnancy and lactation has a damaging effect.

### **Driving and using machines**

Helicobacter Test *INFAI* has no influence on the ability to drive or to use machines.

## **3. How to take Helicobacter Test *INFAI***

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You should perform the test in the presence of your doctor or another qualified person.

### **The recommended dose is**

Patients from the age of 12 must take the content of one jar for one test.

### **Method of use**

You must have fasted for 6 hours before application, preferably overnight. Ask your doctor, if fasting is a problem, for example for diabetic patients.

The test procedure lasts approximately 40 minutes.

The test should be performed following at least:

- 4 weeks after a therapy against a bacterial infection
- 2 weeks after the last administration of a medicine to reduce release of stomach acid

Both groups of medicines could influence the results of the Helicobacter Test *INFAI*. This is particularly after a therapy to remove *Helicobacter pylori*. It is

important to follow the instructions for use exactly, otherwise the result may be questionable.

### **Essential items not supplied with Helicobacter Test *INFAI***

Before the breath test is performed a liquid test meal is taken to delay the stomach from emptying. The test meal is not provided within the kit. The following are suitable test meals:

- 200 ml 100 % orange juice or
- 1 g citric acid dissolved in 200 ml water

If you cannot take either of these test meals, please tell your doctor, who will suggest an alternative. A drinking vessel and tap water is required to dissolve the <sup>13</sup>C-urea powder. If the test needs to be repeated, this should be done on the following day at the earliest.

### **Special instructions for use** (for infrared spectroscopy)

The test is to be performed after instruction by a healthcare professional and under appropriate medical supervision. The patient data should be documented using the provided data sheet. It is recommended that you take the test in a resting position.

1. The test should be carried out after having fasted 6 hours before application, preferably overnight. If the test needs to be carried out later in the day, only a light meal like tea and toast is recommended.
2. The test begins with the collection of samples for determining the baseline values:
  - The straw and the breath bag labelled “sampling time: 00-minute-value” are taken from the test set.
  - The stopper is removed from the breath bag and place the unwrapped straw into the breath bag.
  - Now the patient breathes gently through the straw into the breath bag.
  - The patient must continue to breathe through the straw while removing it from the breath bag, and then immediately seal the breath bag with its stopper.

If the breath bag remains open for more than 30 seconds, the result could be inaccurate.

- The breath bag should be held upright and the bar-code label marked “00-minute-value” will be stuck on the breath bag.
3. Then the patient must drink the recommended test meal (200 ml 100 % orange juice or 1 g citric acid in 200 ml water).
  4. Now the preparation of the test solution follows.
    - The jar labelled “<sup>13</sup>C-urea powder” is removed from the test set, opened, and filled up to about three quarters with tap water.
    - The jar is closed and carefully shaken until all the powder has dissolved completely.
    - The contents are poured into a drinking glass, the jar filled a second and third time with water and the contents transferred into the drinking glass, so that approximately 30 ml of test solution is obtained.
  5. The patient should drink this test solution immediately. The time of intake must be noted.
  6. 30 minutes after the test solution has been taken (point 5), the “30-minute-value” sample is collected in the breath bag, which remains in the pack (labelled “sampling time: 30-minute-value”) as described under point 2.

The bar-code label marked “30-minute-value” must be used for this sample.
  7. The corresponding bar-code label must be put on the data sheet for patient documentation. All breath bags should be placed back into the original packaging. This packaging should be sealed with the remaining sticker.
  8. The package must be sent to a qualified laboratory for analysis.

Medical or healthcare professionals can find detailed information on the analysis of breath samples and the testing specifications for laboratories, in section 6.6 of the Summary of Product Characteristics.

### **If you take more Helicobacter Test *INFAI* than you should**

Because only 75 mg <sup>13</sup>C-urea is provided overdose is not to be expected.

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

### **4. Possible side effects**

No side effects are known.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. You can also report side effects directly via the national reporting system:

### **United Kingdom**

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

### **Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Helicobacter Test *INFAI***

Keep this medicine out of the sight and reach of children.

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

Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What *Helicobacter Test INFAI* contains

- The active substance is <sup>13</sup>C-urea.  
One jar contains 75 mg <sup>13</sup>C-urea.
- There are no other ingredients.

### What *Helicobacter Test INFAI* looks like and contents of the pack

*Helicobacter Test INFAI* is a white, crystalline powder for oral solution.

Content of the test kit with 1 jar:

No.	Component	Quantity
1	Jar (10 ml volume, polystyrene with polyethylene snap cap) containing 75 mg <sup>13</sup> C-urea powder for oral solution	1
2	Breath bags: Sampling time: 00-minute-value Sampling time: 30-minute-value	1 1
3	Bendable straw for collection of the breath samples into the corresponding breath bags	1
4	Data sheet for patient documentation	1
5	Package leaflet	1
6	Page of barcode labels and sticker	1

### Marketing Authorisation Holder

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### Manufacturer responsible for batch release

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

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**This leaflet was last revised in 05/2021.**

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