

PACKAGE LEAFLET
Package leaflet: Information for the user

**HeliCap 37 kBq capsules, hard
urea (¹⁴C)**

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

1. What HeliCap is and what it is used for

This medicine is for diagnostic use only. The capsule is a part of a breath test examination that can be used to determine whether or not you have an infection in the stomach and/or duodenum caused by the bacterium *Helicobacter Pylori*.

HeliCap contains urea (¹⁴C), which is mildly radioactive. Following the intake of HeliCap your breath is collected and analysed. You are infected with *Helicobacter Pylori* if traces of radioactivity is found in your breath.

The amount of radioactivity per capsule is low and has a very short range. In plastic, the range is 0.25 mm, and will not penetrate its standard container. This is considerably less than what you would receive from a normal X-ray examination of the stomach.

2. What you need to know before you take HeliCap

Do not take HeliCap

- if you are allergic (hypersensitive) to urea (¹⁴C) or any of the other ingredients of HeliCap
- if you have any infection in the stomach, as it may cause a false result
- if you are pregnant

Warnings and precautions

- if you have had your whole stomach or part of your stomach removed
- if you are below 18 years of age

Other medicines and HeliCap

HeliCap may be affected by other medicines. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- The risk for obtaining wrong diagnosis is increased if the test is performed within four weeks after using antibiotics or bismuth salts and within one week after the last dose of acid reduction treatments.

HeliCap with food and drink and alcohol

You should not eat for at least 6 hours, preferably overnight before taking the HeliCap capsule, also drinks containing sugar or calories (e.g. fruit juice, lemonade) should be avoided. You may drink some water up to the time the test is performed.

Pregnancy and breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

You must not use this test if you are pregnant, trying to be pregnant, or think you may be pregnant.

If you are breast-feeding and the test is deemed to be necessary, you should stop breast-feeding for three days following the test. Pumped milk should be discarded.

Driving and using machines

HeliCap has no known effects on the ability to drive or to use machines.

3. How to take HeliCap

The test should be performed in the presence of a registered nurse or doctor.

You should be fasting for at least six hours before the test is performed.

The diagnosis is based on the analysis of your breath after you have swallowed the capsule. The usual dose is one capsule as a single dose. The capsule should be swallowed as whole with a small glass of water. If the capsule is chewed, the test must be performed again as the risk of false results increase. A new test may be performed at the earliest the following day.

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

If you take more HeliCap than you should

Since HeliCap is administered by healthcare personnel under strict controlled conditions, an overdose is not expected.

4. Possible side effects

HeliCap has no known side effects. If you notice any side effects, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store HeliCap

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

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

Do not store above 25°C. Keep the container tightly close in order to protect from moisture.

Radioactive waste shall be disposed of in accordance with local requirements.

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 HeliCap contains

- The active substance is urea (^{14}C). Each capsule contains 37kBq (kiloBecquerel – the unit in which radioactivity is measured) of urea (^{14}C).
- The other ingredients are citric acid anhydrous, gelatine, indigo carmine (E 132), and titanium dioxide (E 171).

What HeliCap looks like and contents of the pack

Capsule, hard.

The capsule is blue, 6 x16 mm.

Pack size: 10 capsules/bottle

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Laboratoires Mayoly Spindler
3 Place Renault
92500 Rueil-Malmaison
France

Manufacturer

Institute of Isotopes Co. Ltd
Konkoly Thege út 29-33
H-1121 Budapest
Hungary

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	HeliCap 37kBq - Hartkapseln
Portugal	HeliCap
Sweden	HeliCap
The Netherlands	HeliCap

This leaflet was last revised in July 2025.