

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about HELICAP.

- What HeliCap® is and what it is used for
- Before you take HeliCap®
- How to take HeliCap®
- Possible side effects
- How to store HeliCap®
- Further information

It does not contain all the information that is known about HELICAP.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of taking HELICAP against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

Keep this leaflet - you may need to read it again.

What HELICAP is and what it is used for

HELICAP® 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 a primary or remaining infection in the stomach caused by the bacterium *Helicobacter Pylori*.

HeliCap® contains ¹⁴C -urea, which is mildly radioactive. The test uses the bacterium's ability to break down urea into carbon dioxide. Following the intake of HeliCap® your breath is collected and analysed. You are infected with *Helicobacter Pylori* if traces of radioactivity are found in your breath.

How HELICAP works

- HELICAP is swallowed with a glass of water on an empty stomach.
- HeliCap containing ¹⁴C -labelled urea disintegrates rapidly in the stomach area and the ¹⁴C -urea is dissolved.
- In the presence of *Helicobacter Pylori*, the ¹⁴C -urea is metabolized to carbon dioxide and ammonia by the enzyme urease which is produced by the bacteria.
- The available ¹⁴C isotopes, now in the form of carbon dioxide (¹⁴CO₂), diffuse into the blood to be transported to the lungs, where it is exhaled in the breath and captured during sampling. A positive sample is conclusive evidence of *Helicobacter Pylori* infection.
- In the absence of *Helicobacter Pylori* the administered ¹⁴C -urea is absorbed in the gastrointestinal tract and subsequently voided.

Before you use HELICAP

Before you use it:

You must tell your doctor if:

- You have allergies to HELICAP or any of the other ingredients in this product.
- You have documented or suspected other gastric infection or atrophic

gastritis. These conditions can interfere with the test.

- You are pregnant.

If you have not told your doctor any of the above things, please tell the doctor before taking HELICAP.

When you must not take it:

Do not use HELICAP if you are pregnant or breastfeeding.

Although the radiation dose is very low, the test is contraindicated in pregnant women. 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.

Do not use HELICAP if you are allergic (hypersensitive) to ¹⁴C-urea 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 have had your whole stomach or part of your stomach removed

Do not give HELICAP to children.

There is no data to support the safety of HELICAP in children.

Do not use HELICAP after the expiry date printed on the pack, or if the packaging is damaged or torn.

Using other Medicines

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 (4) weeks after using antibiotics and within one (1) week after the last dose of acid reduction treatments.

Driving and using machines

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

Important information about some of the ingredients of HeliCap®

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. The effective dose equivalent you will receive from taking one HeliCap® capsule (one diagnostic test) is less than 3.0 microSv. This is considerably less than what you would receive from a normal X-ray examination of the stomach.

Using HELICAP

How to take it:

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

Stepwise description of the test procedure

- You should be fasting for at least six (6) 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.
- Wait for 10 minutes.

- You will receive a BreathCard® that contains a mouthpiece into which you should exhale.
- Exhale into the BreathCard® until the complete surface of the round orange indicator has turned yellow. This will take approximately 1-2 minutes. You can pause to rest for a few breaths without affecting the test results.
- Please note!** You must not inhale through the BreathCard® since it contains a substance that may cause some irritation to the respiratory tract.
- If your doctor has access to an analyser in his/her office you will receive the results within a few minutes.

Overdose

Because only one (1) capsule is provided per test, no overdose is expected.

Contact the Poisons Information Centre (Australia 131126, New Zealand 0800764766)

While you are using HELICAP

- If you have any further questions about HELICAP, please ask your doctor or pharmacist.

Side effects

All medicines can cause side effects, although not everybody gets them.

HeliCap® has no known side effects. If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

After using HELICAP

Storage

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.

Keep out of the reach and sight of children. Store below 25°C. Store in original package.

Keep the container tightly closed in order to protect from moisture.

Disposal

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

Product description

What it contains

The active substance is ¹⁴C-urea 37kBq, which is equivalent to approximately 1 to 2 microgram (1 to 2 parts per million of a gram) ¹⁴C-urea per capsule.

The other ingredients are citric acid, gelatin, indigo carmine (E 132), and titanium dioxide (E 171).

What it looks like:

Capsule, hard. The capsule is blue, 6mm x16 mm.

HELICAP capsules come in packs of 10 capsules in white, 15 ml polyethylene containers which are sealed with white polyethylene snap-on caps.

Sponsor

Vitramed Pty Ltd
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