

Package leaflet: Information for the user
Espikur 50 mg tablets
¹³C-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 Espikur is and what it is used for
2. What you need to know before you take Espikur
3. How to take Espikur
4. Possible side effects
5. How to store Espikur
6. Contents of the pack and other information

1. What Espikur is and what it is used for

This medicine is for diagnostic use only.

Espikur is a breath test. After you have taken the tablet your breath test will show if you are infected by the bacterium *Helicobacter pylori* in the stomach.

Why do you need to take the Espikur test? You may have a gastric infection caused by a bacterium called *Helicobacter pylori*. Your doctor has prescribed the test for one of the following reasons:

- Your doctor wants to confirm whether you are suffering from *Helicobacter pylori* infection.
- You have already been determined as being infected by *Helicobacter pylori* and have been taking medication aimed cure the infection. Your doctor will now check if the treatment has been successful.

2. What you need to know before you take Espikur

Do not take Espikur:

- if you are allergic to ¹³C-urea or any of the other ingredients of this medicine (listed in section 6).
- if you have or suspect to have an infection in the stomach as it may cause false results.
- if you have an inflammation of the stomach lining (atrophic gastritis) as it may cause false results.

Warnings and precautions

Talk to your doctor or pharmacist before taking Espikur if you have complete or partial removal of the stomach.

Other medicines and Espikur

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

The test should not be performed within at least:

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

Both groups of medicines could influence the results of the test. This is particularly relevant after a therapy against *Helicobacter pylori* bacterium.

Pregnancy and breast-feeding

It is not expected that performing the breath test during pregnancy and breast-feeding has a damaging effect. Espikur can be used during pregnancy and breast-feeding.

Driving and using machines

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

3. How to take Espikur

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

You should be fasting for at least 6 hours before the breath test is performed. You may drink some water up to the time the test is performed.

Some medicines can affect the test result. See section “Other medicines and Espikur”.

The test procedure takes approximately 10 minutes.

The recommended dose is one tablet as single dose. The tablet should be swallowed as whole with a glass of water. If the tablet is chewed, the test must be performed again as the risk of false result increase.

A new test may be performed at the earliest the following day.

This medicine should not be administered to children younger than 18 years due to insufficient data.

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

If you take more Espikur than you should

Because only 1 tablet is provided, no overdose is expected. If you are uncertain, please contact your doctor.

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them.

Very rare (may affect up to 1 in 10.000 people)

- stomach pain
- fatigue
- distortion of the sense of smell (parosmia)

If any of the side effects gets serious, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or 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.

[To be completed nationally]

5. How to store Espikur

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.

Store in the original package in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Espikur contains

- The active substance is ^{13}C -urea. Each tablet contains 50mg ^{13}C -urea.
- The other ingredients are: anhydrous citric acid, colloidal anhydrous silica, croscarmellose sodium, microcrystalline cellulose, magnesium stearate and talc.

What Espikur looks like and contents of the pack

Espikur is a white round convex tablet, 12 mm in diameter.

Pack sizes:

1 tablet (kit) in aluminium blister (with sample tubes and disposable straw).

10 x 1 tablet in aluminium blister (without sample tubes and disposable straw).

Breath bags are provided separately.

Component	1 tablet (kit)	10 x 1 tablet
Tablet in an aluminium blister	1	10
Sample tubes for 00-minute breath sample (blue stopper)	2	-
Sample tubes for 10-minute breath sample (red stopper)	2	-
Disposable straw	1	-
Package leaflet	1	1
Barcode labels for the sample tubes	4	-
Extra barcode labels	2	-

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Laboratoires Mayoly Spindler
3 Place Renault
92500 Rueil Malmaison
France

Manufacturer

Laboratoires Mayoly Spindler
6, Avenue de l'Europe
78400 Chatou
France

Or

Laboratoires Galeniques Vernin
20 Rue Louis Charles Vernin
Dammarié Les Lys, 77190
France

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

Belgium, Luxemburg, Portugal, Spain, Sweden, The Netherland:	Espikur 50 mg
Italy:	Helidiag 50 mg

This leaflet was last revised in 2 October 2025.

Detailed information on this medicine is available on the website of [name of MS Agency \(link\)](#)

The following information is intended for healthcare professionals only:

It is recommended to perform the test with the patient being in a resting position.

If the test is to be carried out in the morning, the patient should fast overnight and not eat breakfast. If the test is to be carried out later in the day, or if fasting may cause some problems for the patient, then only a light breakfast, e.g. tea and toast, is allowed. Also, if the patient has eaten a heavy meal then it will be necessary to fast for six hours prior to the test.

The collection of breath samples can be performed using tubes or breath bags.

Test procedure using sample tubes (see figure 1).

To perform the test, 4 sample tubes with stoppers and 1 straw are used.

Keep one of the extra barcode labels as a reference label for the patient's journal.

1. The patient should begin the procedure with the two 00-MINUTES sample tubes with blue stopper.

- Unscrew the stopper.
- Place the straw in the bottom of the sample tube.
- Take a deep breath and exhale gently into the tube.
- Remove the straw from the tube and close the tube with the stopper immediately.
- Check that the stopper is properly closed.
- Repeat the test with the second 00-MINUTES sample tube

2. Swallow the tablet with a glass of water. Wait for 10 minutes in an upright position (standing or sitting position).

3. Exhale into the two 10-MINUTES tubes with red stoppers in the same way described above.

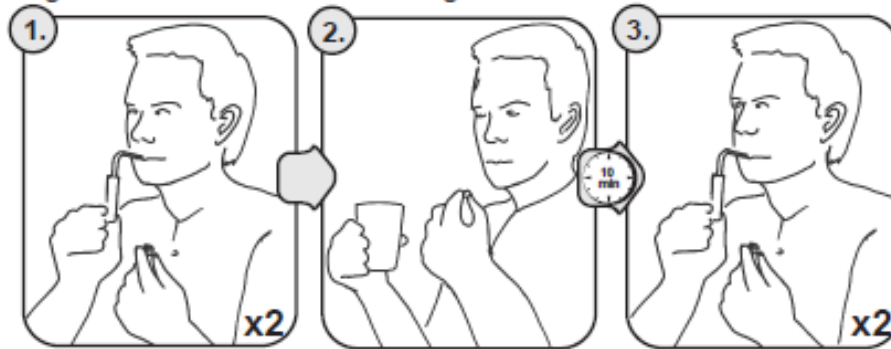
After the collection of samples, the 4 tubes should be labelled as per the image below, with one barcode label being placed lengthways on each tube.

Forward the 4 labelled sample tubes for analysis to the local diagnostic laboratory.

Handle the sampled tubes with care and avoid any damage which may cause leakage.

Figure 1. How to take the test using sample tubes

Figure 1. How to take the test using test tubes.



Test procedure using breath bags (see figure 2).

To perform the test, 2 single breath bags or 1 double bag and 1 mouth piece are used.

1. Remove the stopper cap from the breath bag hose and connect a mouth piece to the hose. Exhale through the mouth piece for the baseline (00-MINUTE) breath bag sample. Remove the mouth piece from the breath bag and close the breath bag with the stopper cap.
2. Swallow the tablet with a glass of water. Wait for 10 minutes in an upright position (standing or sitting position).
3. Exhale into the unused side of the double breath bag or to another single breath bag for the test (10-MINUTES) breath bag sample in the same way as described above.

Mark the breath bags in order to identify the different samples (e.g. “zero test” and “10 min test”).

Handle the sampled breath bags with care and avoid any damage which may cause leakage.

Figure 2. How to take the test using breath bags.

