

Diabact UBT

50mg tablets ¹³C-urea

Consumer Medicine Information

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 symptoms are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Diabact UBT is and what it is used for
2. Before you take Diabact UBT
3. How to take Diabact UBT
4. Possible side effects
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1. What Diabact UBT is and what it is used for

This medicine is for diagnostic use only to determine the presence of *Helicobacter pylori*. Diabact UBT is a breath test 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*.

2. What you need to know before you take Diabact UBT

Do not take Diabact UBT

- if you are allergic (hypersensitive) to ¹³C-urea or to any of the other ingredients of Diabact UBT.
- if you have an infection in the stomach, as it may cause a false result.

Other medicines and Diabact UBT

Diabact UBT 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 two (2) weeks after the last dose of acid reduction treatments.

Taking Diabact UBT with food and drink

- You should not eat for at least 6 hours before the test is performed. You may drink some water up to the time the test is performed.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. It is not expected that performing the breath test during pregnancy and lactation has a damaging effect.

Driving and using machines

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

3. How to take Diabact UBT

Always take Diabact UBT exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should be fasting for at least 6 hours before the test is performed. The usual 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 results increase. A new test may be performed at the earliest the following day.

Stepwise description of the test procedure

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

1. You should begin the procedure with the two 00-MINUTES test tubes with blue stopper.
 - Unscrew the stopper
 - Place the straw in the bottom of the test tube
 - Take a deep breath and blow gently into the tube.
 - Remove the straw from the tube and close the tube with the stopper.
 - Check that the stopper is properly closed.
 - Repeat the test with the other 00-MINUTES test tube
2. Swallow the tablet with a glass of water.
3. Wait for 10 minutes in an upright position (standing or sitting)
4. Blow into the two 10-MINUTES tubes with red stoppers in the way described above.

After the test has been performed, the tubes should be placed in the box, if the Diabact UBT kit is used. The address of the testing laboratory is to be filled in on the designated place on the underside of the box.

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

If you take more Diabact UBT than you should

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

4. Possible side effects

Like all medicines Diabact UBT can cause side effects, although not everybody gets them.

Taste disturbance has been commonly reported. Stomach pains, nausea, vomiting, fatigue and distortion of the sense of smell (parosmia) have also been reported. These effects are usually mild and short-lived.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you are experiencing an adverse event or think you may be experiencing one, including any possible side effects not listed in this leaflet, please seek advice from a doctor or pharmacist as soon as possible. The adverse event should then be reported in accordance with the Australian Adverse Drug Reaction Reporting System (<https://www.ebs.tga.gov.au/ebs/ADRS/ADRSRepo.nsf?OpenDatabase>).

If you need urgent medical help call 000. If you have experienced an overdose or suspected

poisoning, call the Poisons Information Centre, 24 hours a day on 13 11 26.

5. How to store Diabact UBT

Keep out of the reach and sight of children.

Do not use Diabact UBT 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 to protect from light.

Store below 25°C.

Tablets individually sealed in foil. Do not use if foil is broken.

Do not dispose of medicine via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Diabact UBT contains

- The active substance is ¹³C-urea enriched stable isotope. Each tablet contains 50 mg ¹³C-Urea
- The other ingredients are anhydrous citric acid, colloidal anhydrous silica, croscarmellose sodium, microcrystalline cellulose, magnesium stearate and talc.

What Diabact UBT looks like and contents of the pack

Diabact UBT is a white round convex tablet.

Pack sizes:

1 tablet (kit)

10 x 1 tablets (without sample tubes and disposable straw).

Component	1 tablet (kit)	10 x 1 tablet
Tablet in a 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	
Patient information	1	1
Extra bar code labels	2	

EU Marketing Authorisation Holder

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

Diabact UBT (SE)

Diabact UBT 50mg Tabletten (AT), (DE)

Diabact UBT 50mg Tablet (UK), (IE)

Diabact UBT 50mg (DK), (FI), (NO)

This leaflet was revised in February 2016

**AUST R 135657 DIABACT UBT 13C urea
tablet blister pack with other components kit;**

**AUST R 146728 DIABACT UBT 13C urea 50
mg tablet blister pack**