

Information for the user

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 Diabact UBT is and what it is used for
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3. How to take Diabact UBT
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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 to ¹³C-urea or any of the other ingredients of this medicine.
 - 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. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- 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.

Diabact UBT with food, drink and alcohol
- 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, breast-feeding and fertility
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
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. 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
 - move 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 medicine, 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, this medicine can cause side effects, although not everybody gets them. Stomach pain, fatigue and distortion of the sense of smell (parosmia) have been reported.
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 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 Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard (United Kingdom) or via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie e-mail: imbpharmacovigilance@imb.ie (Ireland).
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Diabact UBT
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 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	

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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 50 mg Tabletten (AT), (DE)
Diabact UBT 50 mg Tablet (UK), (IE)
Diabact UBT 50 mg (DK), (FI), (NO)

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