

**Package leaflet: Information for the user (UK (NI) + IE)**

**Diabact UBT 50 mg tablets**  
**<sup>13</sup>C-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 Diabact UBT is and what it is used for
2. What you need to know before you take Diabact UBT
3. How to take Diabact UBT
4. Possible side effects
5. How to store Diabact UBT
6. Contents of the pack and other information

**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 <sup>13</sup>C-urea or to any of the other ingredients of this medicine (listed in section 6).
- if you have an infection in the stomach, as it may cause a false result.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Diabact UBT if you have:

- partial removal of the stomach

**Children and adolescents**

This medicine should not be used in children and adolescents younger than 18 years due to insufficient data.

**Other medicines and Diabact UBT**

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.

**Pregnancy and breast-feeding**

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

### **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 breath test is performed. You may drink some water up to the time the test is performed.

The test procedure takes approximately 10 minutes.

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.

#### **If you take more Diabact UBT than you should**

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

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

### **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 the national reporting system :

United Kingdom (Northern Ireland):

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Diabact UBT contains**

- The active substance is  $^{13}\text{C}$ -urea enriched stable isotope. Each tablet contains 50mg  $^{13}\text{C}$ -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 in aluminium blister, 2 sampling tubes with blue stopper and 2 sampling tubes with red stopper, 1 disposable straw, 4 barcode labels for the 4 sampling tubes and 2 extra barcode labels.  
10 x 1 tablets in aluminium blister (tablets only).

### **Marketing Authorisation Holder**

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

### **Manufacturer**

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

### **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 (NI)), (IE)  
Diabact UBT 50 mg (DK), (FI), (NO)

**This leaflet was last revised in February 2023.**

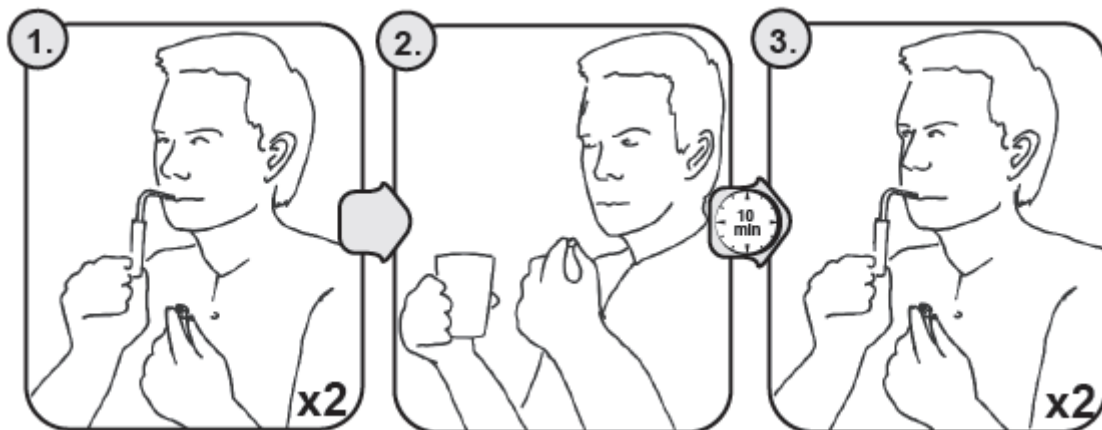
-----  
The following information is intended for healthcare professionals only:

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 is a problem for the patient, then a light breakfast only, e.g. tea and toast, is recommended. 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. Breath bags are provided separately.  
Handle sampled tubes and breath bags with care and avoid any damage which may cause leakage.

***Stepwise description of the test procedure using tubes***

To perform the test, 4 sampling tubes with stoppers and 1 straw are used.  
Keep one of the extra barcode labels as a reference label for the patient journal.



1. The patient should begin the procedure by exhaling into the two baseline (00-MINUTES) tubes (blue stopper).
  - Unscrew the stopper and place the straw in the bottom of the sampling tube.
  - Take a deep breath and exhale 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 sampling 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 (red stopper) in the way as described above.

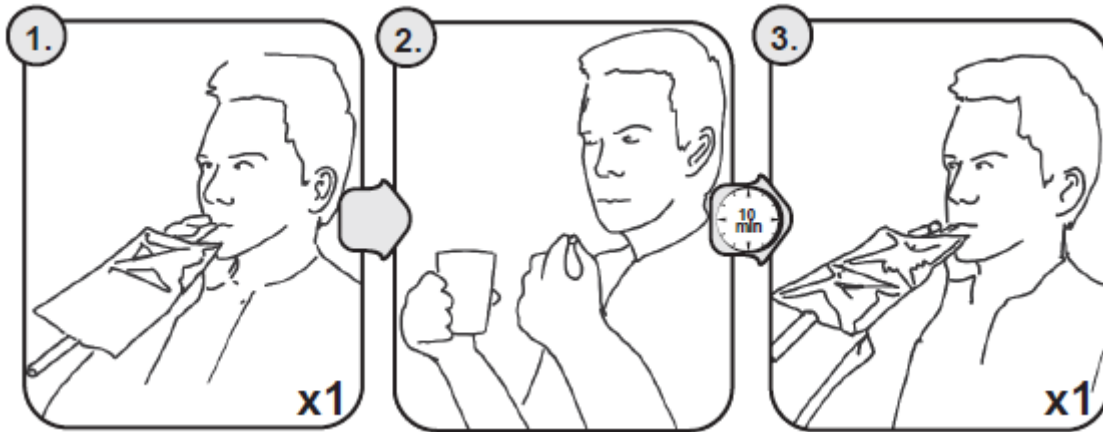
After the test has been performed, the 4 sampling tubes should be labelled as per the image below, with one barcode label being placed lengthways on each tube.



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

***Stepwise description of the test procedure using breath bags***

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



1. The patient should begin the procedure by exhaling through the mouth piece for the baseline (00-MINUTE) breath bag.
  - Remove the stopper cap from the breath bag hose and connect a mouth piece to the hose. Take a deep breath and exhale into the mouth piece which is connected to the breath bag.
  - Remove the mouthpiece 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 10-MINUTES sample in the same way as described above.

Label the breath bags in order to identify the different samples (e.g. “00-MINUTE” and “10-MINUTE”).