Information for the user

Read all of this leaflet carefully before you start taking this medicine because it contains important information about your treatment.

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 this leaflet about?

1. What Diabact UBT is and what it is used for

Diabact UBT is a medicine that can be used to confirm or rule out infected by Helicobacter pylori, a type of bacteria that can cause stomach problems. It is used as a diagnostic tool to test for the presence of 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:

Do not take Diabact UBT if:

- you are allergic to 13C-urea or any of the other ingredients.
- you have a gastric or duodenal ulcer.
- you have a disease that has caused abnormal blood sugar levels.
- you have problems with your stomach or intestines.
- you have an infection in the stomach, as it may cause a false result.

3. How to take Diabact UBT

Always take Diabact UBT exactly as your doctor has prescribed. The usual dose is one tablet as instructed. If you have any questions about how to take this medicine, please ask your doctor or pharmacist.

4. Possible side effects

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

- Stomach pain, fatigue and disturbance of the sense of smell (parosmia) have been reported.
- If any of the side effects gets worse, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reported by patients

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 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 6765157, 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.

Store the medicine in an easily accessible place.

6. Contents of the pack and other information

Diabact UBT is a white round convex tablet.

- The active substance is 13C-urea.
- The other ingredients are anhydrous citric acid, colloidal anhydrous silica, croscarmellose sodium, microcrystalline cellulose, magnesium stearate and talc.

7. Marketing Authorisation Holder

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- Tel: +46 18 780 88 00

8. Manufacturer

Idiopharma AB
Calle Noain N°1
31110 Noain (Navarra)
Spain

This medicinal product is authorised in the Member States of the EEA under the following names: Diabact UBT 50 mg Tabletten (AT), (DE), (SE), (DK), (FI), (NO)

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

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

This leaflet was last revised in January 2016

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**Diabact UBT 50mg tablets 13C-urea**

**Stepwise description of the test procedure**

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

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

2. Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, or you plan to become pregnant, consult your doctor or pharmacist before taking this medicine.

- If you are 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.

3. Driving and using machines

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

4. How to do the Diabact UBT test

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

- The test can be performed at the earliest 3 to 5 hours after the last dose of acid reduction treatments.

- 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.

- The active substance is 13C-urea enriched stable isotope. Each tablet contains 50 mg 13C-urea.

- All other ingredients are anhydrous citric acid, colloidal anhydrous silica, croscarmellose sodium, microcrystalline cellulose, magnesium stearate and talc.

- This medicine has been prescribed for you only. Do not take it if you are not sure.

- The steps below describe the test:

**Component**

<table>
<thead>
<tr>
<th>Component</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tablet in a blister</td>
<td>1 tablet (kit)</td>
</tr>
<tr>
<td>Sample tubes for 00 minute breath sample</td>
<td>10 x 1 tablets (without sample tubes and disposable straw)</td>
</tr>
</tbody>
</table>

**Pack size:**

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