Patient package insert in accordance with the pharmacists' regulations (Preparations, 1986)

The dispensing of this medicine requires a physician's prescription.
Read this package insert carefully in its entirety before using this medicine

^{13}C UREA Tablet

Description: UREA Tablet, enriched with ^{13}C, 75 mg.

Indication: For the diagnosis of *Helicobacter pylori (H. pylori)* presence in the human stomach by breath test, as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection.
For use with a suitable kit (according to the instructions for use in the leaflet provided with the kit).

Composition: Each tablet contains 75 mg of ^{13}C-Urea

Inactive ingredients:
Sodium Benzoate, NF, Povidone, USP (Kollidon 90F), Microcrystalline Cellulose, NF (Avicel 102), Colloidal Silicon Dioxide, NF (Aerosil 200).

Instructions for Use:

Preparation of the drink:
- Dissolve the tablet in 150 mL to 200 mL of tap water together with citric acid ("Citrica") supplied in a separate pouch.
- Stir thoroughly with a straw for 2 to 3 minutes until completely dissolved. However, tiny particles might still be seen in the solution after stirring.
- Alternatively, the tablet may be dissolved in 150 to 200 mL of tap water with 1.4 g of citric acid or orange juice without Citric acid.
- Drink the solution from the glass with a straw.
- Drink the solution within two minutes.

Note:
If substantial particles are still present after 5 minutes of stirring, discard the solution and repeat the procedure with a new tablet. Drink the solution not later than two hours of preparation, as this is the maximal time to maintain solution stability.

Recommendations before the use:
- The patient should have fasted at least 1 hour before administering the solution.
- The patient should not have taken proton pump inhibitors, antimicrobials and bismuth containing preparations within two weeks prior to administering the test, since these medicines suppress the *Helicobacter pylori organism,* and may give a false negative result.

Recommendations at the time of use:
The breath test should be performed within 30 minutes after drinking the solution.
During these 30 minutes no eating, drinking, or smoking is allowed.

Warnings:
For diagnostic use only.
The dissolved solution is taken orally as part of the diagnostic procedure.
In the case of accidental overdose, drink water and immediately contact the poison control emergency center.
A negative result does not rule out the possibility of *H. pylori* infection. False negative results can occur with this procedure.
A false positive test may occur due to to presence of other microorganisms like Helicobacter heilmanni (rare).
A false positive test could occur in patients who have achlorhydria.
If clinical signs suggest H. pylori infection, retest with a new sample or an alternate method.

Limitations of the test:
1. Post treatment monitoring of *H. pylori* should be performed after at least four weeks of treatment for *H. pilori* infection.
2. Safety and effectiveness in patients under the age of 18 years have not yet been established.
3. Data is insufficient for recommending the use of this test on patients with total or partial **gastrectomy**.
4. Data is insufficient to recommend the use of this test on pregnant and lactating women.
5. A correlation between the number of *H. pilori* organisms in the stomach and the BreathID® results has not been established.

Side effects:
In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult with your doctor immediately.

Storage: At room temperature, below 25°C.
Do not use the medicine beyond the expiry date mentioned on the package. The expiry date refers to the last day of that month.

Registration number: 130 45 30942 02

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Manufacturer and registration holder: Meridian Bioscience Israel Ltd., 4 Hamaayan St. Modiin 7177872

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