



**Isodiagnostika**  
a division of Knight Therapeutics Inc.

Manufactured by Isodiagnostika  
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MADE IN CANADA

#### H-Cup - HCUP01

Contains 48 H-Cups (48 plastic screw top containers with pre-mixed  $^{13}\text{C}$  urea powder, 50 mg each)

intended for the diagnosis of *Helicobacter pylori* infection

#### CONTENT OF THE BOX

- 48 H-Cups (48 plastic screw top containers with pre-mixed  $^{13}\text{C}$  urea powder, 50 mg each)

#### SHELF LIFE AND STORAGE

H-Cups should be stored between 15°C and 30°C (59°F to 86°F) and should not be used beyond its expiry date. The breath test samples, if stored between 15°C and 30°C (59°F and 86°F), are stable up to 6 months from the collection date.

#### Notes:

- Carefully read and follow the warnings and precautions listed below prior to using the H-Cup. The H-Cup is intended to be used with other components as a breath test kit for the diagnosis of *Helicobacter pylori* infection.
- For complete information, please refer to <https://www.helikit.com>.

#### DIRECTIONS FOR USE (ASSEMBLED DIAGNOSTIC KIT)

- Step 1: Collect the first breath sample into the collection tube.
- Step 2: Prepare urea solution by adding tap water to the “Fill to 80 mL” line on the plastic container (H-Cup) (about 80 mL). Replace lid on container and mix by shaking vigorously until completely dissolved. Then, have the patient slowly drink the solution. Start timing (30 minutes) the patient once solution has been consumed. Patients **should not** drink or eat anything during this 30 minutes.
- Step 3: 30 minutes after drinking the solution, have the patient **exhale fully** into the collection tube following the same directions as for the first sample (Step 1).
- Step 4: **Analyze** the collected breath samples according to the procedures applicable to the analytical method used.

#### WARNINGS AND PRECAUTIONS

- Intended for patients aged 6 years and older.

- Patients should not eat or drink for at least 4 hours before taking the diagnostic test for *H. pylori* infection, and during the 30-minute wait period.
- The following groups of medications should be discontinued for the following time periods prior to using the diagnostic test, as they may interfere with the test results:
  - Proton Pump Inhibitors (H<sup>+</sup>, K<sup>+</sup> - ATPase Inhibitor) – 3 days
  - Histamine H<sub>2</sub> Receptor Antagonists – 1 day
  - Antibiotics – 4 weeks
  - Bismuth preparations – 2 weeks
- The diagnostic test for *H. pylori* infection should be scheduled prior to barium tests if both are scheduled for the same day.
- No other breath tests should be scheduled at the same time as the diagnostic test for *H. pylori* infection.
- If particulate matter is visible in the reconstituted <sup>13</sup>C urea solution after thorough mixing, the solution should not be consumed.
- For *in vitro* diagnostic use only.