

Consumer Brief Summary about BreathTek UBT

Intended Use

The BreathTek® UBT for *H. pylori* Kit is a breath test that detects a common infection of the stomach called *Helicobacter pylori* (*H. pylori*). A licensed health care practitioner may prescribe BreathTek UBT to test for *H. pylori* infection in patients aged 3 years and older. A patient may need to take the test again 4 weeks after completing antibiotic therapy to monitor whether *H. pylori* has been wiped out.

BreathTek UBT is always administered by a health care practitioner, as ordered by a licensed health care practitioner.

Warnings and Precautions

- BreathTek UBT is an *in vitro* diagnostic test requiring you to provide breath samples and drink a drug solution called Pranactin®-Citric
- If you are sensitive to mannitol, citric acid, or Aspartame, avoid drinking the drug solution (Pranactin-Citric)
- Tell your health care practitioner if you are Phenylketonuric (PKU), as this drug contains Phenylalanine (a component of Aspartame). For reference, 12 ounces of a typical diet cola drink contains approximately the same amount of Phenylalanine
- False negative and false positive results may occur with this test
 - Tell your health care practitioner if you continue to have symptoms. You may need to be retested with a new sample or a different method
- Inaccurate results may be caused by drugs you are taking within 2 weeks prior to this test. These may include:
 - Proton pump inhibitors (PPIs) such as Aciphex® (rabeprazole), Nexium® (esomeprazole), Prevacid® (lansoprazole), Prilosec® (omeprazole), Prilosec OTC® (omeprazole), Protonix® (pantoprazole), Zegerid® (omeprazole/sodium bicarbonate), and Dexilant® (dexlansoprazole)
 - Antibiotics
 - Bismuth-based drugs (Pepto-Bismol®)
- Inaccurate test results can also occur if:
 - The second breath sample is collected too soon
 - You were treated for *H. pylori* with antibiotics, but take your confirmation test with BreathTek UBT less than 4 weeks after completing your therapy
- Tell your health care practitioner if you have trouble swallowing because of a medical or physical condition
- The safety of using the BreathTek UBT Kit during pregnancy and lactation is not established
- BreathTek UBT is not to be used with children under the age of 3

Adverse Events

The following adverse events in adults have been identified: anaphylactic (allergic) reaction, oversensitivity and rash, burning sensation in the stomach, tingling in the skin, vomiting, and diarrhea.

In one study, the following adverse events in children 3 to 17 years old have been identified: throwing up, mouth and throat pain (including irritation, soreness, and burning), unsettled stomach, restlessness, stomach ache/belly pain, and diarrhea. Most of these adverse events were experienced within minutes to hours of ingestion of the drug solution (Pranactin-Citric). In another study, some patients also experienced headache, cough, dry mouth, and acute upper respiratory tract infection.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.