H. pylori? It's in the bag

Time to get the answers you need

Please see BRIEF SUMMARY on pages 10-11 and enclosed Current Package Insert.
If you have stomach issues, it’s important to find out the real cause

You may often have stomach symptoms that you blame on certain foods or stress. Maybe you take over-the-counter medications to get some relief, but it doesn’t last long. Maybe your doctor has already prescribed medication, but you still do not feel better. If you have stomach symptoms that keep returning, it’s time to find out the actual cause to help you get the relief you need.

Figuring out the cause of stomach symptoms may not be easy. Stomach problems such as heartburn, stomach inflammation (gastritis), indigestion (dyspepsia), and peptic ulcer all share similar symptoms, including those shown below, that are common symptoms for *H. pylori* infection.¹ ⁴

You might think it’s just heartburn or indigestion, but the true cause may be something you haven’t considered: infection with *Helicobacter pylori* (pronounced hell-ee-ko-back-ter pie-lore-ee) or *H. pylori*.

Please see BRIEF SUMMARY on pages 10-11 and enclosed Current Package Insert.
What is *H. pylori*?

*H. pylori* is a bacterium that can cause infection in the stomach. Patients infected with *H. pylori* often do not suffer any symptoms related to the infection. However, it can live in the stomach for many years and damage the stomach’s lining (epithelium) and protective mucus. This allows gastric acid to harm the stomach’s wall, which can lead to ulcers.

**H. pylori infection causes**

<table>
<thead>
<tr>
<th>Ulcers</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duodenal Ulcers</td>
<td>More than 90%</td>
</tr>
<tr>
<td>Gastric Ulcers</td>
<td>Up to 80%</td>
</tr>
</tbody>
</table>

*H. pylori* infection can also cause gastritis and dyspepsia and, without proper treatment, these conditions will probably not go away. Clinical studies have linked *H. pylori* infection to an increased risk of developing certain stomach cancers.

*Occurrence rates are undetermined for dyspepsia, 10-15% for ulcers, and ~1% for gastric cancer.*
**H. pylori is a common chronic infection that:**

- Affects nearly 1 in 3 adults and 25% of children in the United States\(^8,9\)
- Is usually contracted in childhood and may spread within families living in close quarters\(^5,10\)

**H. pylori infection can last a lifetime unless it is properly treated\(^{11}\)**

Most people with *H. pylori* do not have symptoms of infection.\(^4\) Others may be tested for *H. pylori* infection because of an existing or past peptic ulcer or if they are thought to be at risk for stomach cancer.\(^4\)

If symptoms occur—like the examples listed on page 2—they usually come from the conditions that *H. pylori* causes. As with many other bacterial infections, antibiotics are prescribed to treat *H. pylori*. Treating the stomach symptoms alone could mask the infection and delay more effective treatment.\(^4\)

**Finding out if you have *H. pylori* infection is simple**

Medical experts agree that people suffering with dyspepsia (indigestion) should be considered for *H. pylori* testing since there is some evidence that shows curing the infection may help ease their symptoms.\(^3,5\)

Don't let stomach symptoms eat away at you. Ask your doctor about a simple test—BreathTek® UBT for *H. pylori*.

Please see BRIEF SUMMARY on pages 10-11 and enclosed Current Package Insert.
**BreathTek UBT® for H. pylori**

BreathTek UBT uses your breath samples to identify if you have an active *H. pylori* infection.

1. **Convenient**—Can be done in your doctor’s office or at a laboratory\(^1\)
   - You should have no food or drink for at least 1 hour before the test and be off antibiotics for 2 weeks before the test

2. **Easy**—Simple to do in just 4 easy steps and includes no invasive procedures, no messy collection cups, and no painful needles\(^1\)
   - Breath samples collected before and shortly after drinking a drug solution are used to test for *H. pylori*

3. **Fast**—Administered in approximately 20 minutes in your doctor’s office or laboratory\(^1\)

4. **Covered**—Most national and regional health plans cover BreathTek UBT

If you are diagnosed with *H. pylori* infection, you’ll most likely be prescribed antibiotics. Because these medications are often prescribed to cure infection, some bacteria may have developed a resistance to certain antibiotics.\(^1\)

**To feel confident that your infection is eliminated, your doctor should retest you with BreathTek UBT.** The retest should be at least 4 weeks after you completed your treatment.\(^5\)

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.
Why is it important to confirm that *H. pylori* is eliminated?

- **Ucers are less likely to return** once *H. pylori* infection is eliminated\(^1\)

- **May be less expensive** to eliminate the infection than staying on medicines to treat the symptoms\(^{13,14}\)

- **May reduce the risk of developing stomach cancer**\(^{4,15}\)

Find out if *H. pylori* is causing your symptoms—ask your doctor to test with BreathTek UBT for *H. pylori*.

Please see BRIEF SUMMARY on pages 10-11 and enclosed Current Package Insert.
Patient Reminder Card

Schedule your follow-up test

First day of antibiotic treatment

(date)

Last day of antibiotic treatment

(date)

Appointment to confirm treatment outcome 4 weeks after completion of antibiotic treatment

(date)
Stomach symptoms? Let your doctor know!

List your stomach symptoms here and share them with your doctor.

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

__________________________________________________________________________

Please see BRIEF SUMMARY on pages 10-11 and enclosed Current Package Insert.
MAKE SURE YOUR TREATMENT WORKED!
ASK YOUR DOCTOR ABOUT RETESTING FOR H. PYLORI INFECTION.
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.

January 2016              05US16IBR0002

Please see enclosed Current Package Insert.

Tell your doctor about your stomach symptoms and ask about BreathTek® UBT for H. pylori.

H. pylori? It’s in the bag

Learn more at BreathTek.com

Please see BRIEF SUMMARY on pages 10-11 and enclosed Current Package Insert.