PYtest®

AUSTR67146

The urea breath test for detecting Helicobacter pylori

Consumer Medicine Information

1. What is the PYtest capsule?

PYtest capsule is a gelatin capsule for oral use containing one microgram of ^{14}C labelled urea which is adsorbed onto the sugar spheres made of maize-starch, sugar and coloured yellow with a dye called fluorescein sodium.

2. What is the PYtest used for?

PYtest (Urea [^{14}C] capsule) is used as a single dose test in the diagnosis of *Helicobacter pylori (H.pylori)* infection in the human stomach. The presence of *H.pylori* infection of the stomach has been linked with inflammation of the stomach, which can give rise to stomach ulcers, and even cancer of the stomach. PYtest is available in a capsule or kit form. PYtest may be performed by the patient unsupervised and returned to TRI-MED or an affiliated laboratory for anlaysis, or performed under supervision when the patient is referred to a laboratory.

3. How does the PYtest work?

The PYtest capsule contains sugar beads coated with small amounts of a chemical called urea. Urea is naturally found in the human body, and the amount in a capsule is much smaller than the head of a pin. The urea in the PYtest has been "labelled" with carbon 14 (^{14}C), so it can be detected after it is taken into the body.

After the patient swallows the capsule, it takes about three minutes to dissolve in the patient's stomach. If the patient has *H.pylori* in his or her stomach, when the ^{14}C-urea (which is released from the capsule) comes into contact with *H. pylori* in the patient's stomach, it is immediately broken down into ^{14}C-carbon dioxide and ammonia. The carbon dioxide is carried to the patient's lungs through the bloodstream and is breathed out. 10 minutes after the patient takes the capsule, a breath sample is collected in a balloon. The breath sample is then analysed to measure the amount of the ^{14}C-carbon dioxide breathed out by the patient.

If ^{14}C is present in the breath, the patient has *H. pylori.* If *H. pylori* is not present in the patient's stomach, the ^{14}C-urea simply washes through the stomach and is passed in the urine.

4. What instructions must I follow before taking the PYtest?

You must not eat or drink (including water) for at least six hours before your test. If you have taken any antibiotics in the past 4 weeks please tell your doctor before taking the test. The test will need to be post-poned until you have been off antibiotics for four weeks.

If you have been taking Sucralfate tell your doctor at least 2 weeks before you go for the breath test.

If you are taking a proton pump inhibitor such as Losec (Omeprzaole), Somac (Pantaprazole) or Zoton (Lansoprazole) you will need to stop taking it for 1 week before the test.

During the test, avoid handling the capsule for an extended period of time and swallow the capsule whole, to ensure optimal performance of the test.

5. What you need to tell your doctor.

Before you have your breath test it is important that you give your doctor information on the following:

Antibiotics: Tell your doctor if you are taking or have taken antibiotics or bismuth containing medicines in the past 4 weeks. (Please read Point 4 of this leaflet carefully).

Other medications you may be taking: Tell your doctor if you are taking any other medication including any bought over the counter from a pharmacy, health food shop or supermarket. **It is especially important to tell your doctor if you have taken any medication for stomach problems or reflux in the past 1 week.**

Allergies: Tell your doctor if you are allergic to any of the ingredients listed in this leaflet.

Pregnancy: If you are pregnant, or think you could be pregnant tell your doctor or specialist before you have the test.

Nursing mothers: Tell your doctor if you are breast-feeding before you have the test.

Paediatrics: PYtest has not been studied in children.

6. What are the unwanted effects of PYtest?

There have been no reported adverse reactions to the PYtest capsule.
Tell your doctor if you do not feel well after taking the PYtest.

7. How safe is the PYtest?

Natural ^{14}C is found in every living thing on earth, including our own bodies. This is what gives rise to "natural environmental radiation". A single PYtest gives a tiny amount of ^{14}C that is equal to 3 microsieverts, which is half the environmental dose of radiation that we receive in a normal day. Compared to the PYtest, a mammogram gives a radiation dose of 940 microsieverts and a chest X-ray gives 32 microsieverts. So, the PYtest is 10 times safer than a chest X-ray and 300 times safer than a mammogram.

Every person living anywhere in the world is subject to a small inevitable dose of unavoidable (environ-mental) radiation. Just like we measure the length of an object in centimeters or millimeters , radiation doses are measured in microseieverts. Every person living in Australia gets a daily dose of 6 microsieverts natural (background) environmental radiation during 24hrs.

Although the PYtest contains a tiny amount of radiation it is less than the unavoidable radiation an average person receives every day from natural environmental (or "background") radiation.

8. Can one overdose with the PYtest capsule?

When the test is performed according to the set instructions, an overdose is not likely.

9. How should the PYtest capsule be stored?

The Pytest capsule should be stored below 30°C a secure location. The PYtest capsule has a shelf life of three years from the date of manufacture. The expiry date is printed on the capsule label. The PYtest capsule should not be used after the expiry date.

10. How do I get further information?

A prescription is not required for the PYtest. Ask your doctor if you want to know more information about the PYtest or contact TRI-MED.

The PYtest is distributed in Australia by TRI-MED Distributors Pty Ltd.

This Information Leaflet was first prepared as approved by the TGA on 26th October 2000.

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