

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using PYTEST?

The PYtest capsule contains the active ingredient Urea C14. The PYtest capsule is used to detect gastric urease as an aid in the diagnosis of Helicobacter pylori infection in the stomach.

For more information, see Section [1. Why am I using PYTEST?](#) in the full CMI.

2. What should I know before I use PYTEST?

Do not use if you have ever had an allergic reaction to the PYtest capsule or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use PYTEST?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with the PYtest and affect how it works and produce false results.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use PYTEST?

- The PYtest capsule will be administered under the supervision of a doctor, pathologist or healthcare professional who will instruct you on how to use the PYtest capsule
- The PYtest capsule must be taken on an empty stomach, therefore you must not eat or drink anything (including water) for at least 4 hours prior to the test.
- The dosage for adults is one capsule, swallowed whole with 20 mL water initially. Do not chew the capsule.

More instructions can be found in Section [4. How do I use PYTEST?](#) in the full CMI.

5. What should I know while using PYTEST?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using the PYtest capsule.• Tell your doctor, pathologist or healthcare professional straight away if you feel unwell or are worried about any symptoms or conditions you have.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how the PYtest affects you.
Looking after your medicine	<ul style="list-style-type: none">• Generally, PYtest capsule will be stored by your pathologist prior to use.

For more information, see Section [5. What should I know while using PYTEST?](#) in the full CMI.

6. Are there any side effects?

There have been no reported side effects in patients using the PYtest capsule. If you notice anything that may be making you feel unwell tell your doctor, pathologist pharmacist or healthcare professional.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

PYTEST®

Active ingredient(s): Urea C14

Consumer Medicine Information (CMI)

This leaflet provides important information about using the PYtest. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using PYtest.**

Where to find information in this leaflet:

- [1. Why am I using PYTEST?](#)
- [2. What should I know before I use PYTEST?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use PYTEST?](#)
- [5. What should I know while using PYtest](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using PYTEST?

PYtest capsule contains the active ingredient Urea C14.

The PYtest capsule is a gelatin capsule which contains C14 labelled urea adsorbed onto sugar spheres and coloured yellow with a dye called fluorescein sodium.

PYtest is used to detect gastric urease as an aid in the diagnosis of Helicobacter pylori (H. pylori) infection in the human stomach.

The urease enzyme is not present in human cells, so the presence of urease in the stomach is evidence that bacteria are present. The presence of urease is not specific for H. pylori, but other bacteria are not usually found in the 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..

2. What should I know before I use PYTEST?

Warnings

Do not use PYTEST if:

- you are allergic to urea C14, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- take any medicines for any other condition, particularly in the last 4 weeks.
- have taken any medication for stomach problems or reflux in the past 7 days.
- have achlorhydria which is a condition where your stomach does not produce hydrochloric acid.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

PYtest has not been studied in children.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with PYtest and affect how it works and produce false results.

Tell your doctor if you have taken any antibiotics or medicines containing bismuth in the past 4 weeks before taking the test. The test will need to be postponed until you have been off these medicines for four weeks.

Tell your doctor if you have been taking Sucralfate in the 2 weeks before the test.

Tell your doctor if you are taking a proton pump inhibitor such as Losec (Omeprazole), Somac (Pantaprazole) or Zoton (Lansoprazole). You will need to stop taking these medicines for 1 week before the test. Consult your doctor before stopping any medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect PYtest.

4. How do I use PYTEST?

How much to take

- The doctor, pathologist or healthcare practitioner administering the test will explain how the PYtest capsule is administered.
- The PYtest capsule must be taken on an empty stomach, therefore you must not eat or drink anything (including water) for at least 4 hours prior to the test.
- The dosage for adults is one capsule, swallowed whole with 20 mL water. Do not chew the capsule.
- During the test, avoid handling the capsule as this may interfere with the test result.
- After a few minutes, you will be instructed to drink another 20 mL water to ensure the PYtest capsule has reached your stomach.

When to take the PYtest capsule

- The doctor, pathologist or healthcare practitioner administering the test will explain when to take the PYtest capsule.
- You should be sitting at rest when swallowing the capsule.

After you take the PYtest capsule

- After swallowing the capsule, it takes about three minutes for the capsule to dissolve in your stomach.
- If H.pylori is present in the stomach, when the 14C-urea (which is released from the capsule) comes into contact with H. pylori, it is immediately broken down into 14C-carbon dioxide and ammonia. The carbon dioxide is carried to your lungs through the bloodstream and is breathed out.
- Ten minutes after you take the capsule, a breath sample is collected in a balloon.
- The breath sample is analysed to measure the amount of the 14C-carbon dioxide breathed out.

If you use too much PYtest

The PYtest capsule is administered under the supervision of a doctor, pathologist or other healthcare professional so it is unlikely you will use too much. However, if you think that you have used too many PYtest capsules, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using PYTEST?

Tell your doctor, pathologist or healthcare professional straight away if you:

- Feel unwell or are worried about any symptoms or conditions you have.

Remind any doctor, dentist or pharmacist you visit that you have used the PYtest.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how the PYtest affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Generally, you will not be asked to store PYtest. However, if you are, you should follow the instructions on the carton on how to take care of the medicine properly.

PYtest should be stored in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

There have been no reported side effects in patients using the PYtest capsule.

Tell your doctor or pharmacist if you notice anything that may be making you feel unwell.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What PYtest contains

Active ingredient (main ingredient)	Urea [C14]
Other ingredients (inactive ingredients)	Starch Sucrose Fluorescein sodium Capsule Shell: Empty Gelatin Capsule size 3 Natural TR- Natural TR
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What PYtest looks like

PYtest capsules can be supplied in unit dose packages of 1, 10 and 100 (Aust R 491430).

Not all pack sizes are marketed.

The PYtest capsules can also be supplied as a kit which also includes the breath collection accessories.

Who distributes PYtest

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