

# PTU™ 50 mg Tablets

## 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 PTU™ 50 mg Tablets?

PTU contains the active ingredient propylthiouracil. PTU is used to treat an overactive thyroid gland.

For more information, see Section [1. Why am I using PTU™ 50 mg Tablets?](#) in the full CMI.

### 2. What should I know before I use PTU™ 50 mg Tablets?

Do not use if you have ever had an allergic reaction to PTU 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 PTU™ 50 mg Tablets?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with PTU and affect how it works.

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 PTU™ 50 mg Tablets?

- Your doctor will tell you how many tablets to take, and when to take them each day.
- Follow all directions given to you by your doctor or pharmacist carefully.
- If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

More instructions can be found in Section [4. How do I use PTU™ 50 mg Tablets?](#) in the full CMI.

### 5. What should I know while using PTU™ 50 mg Tablets?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Remind any doctor, dentist, pharmacist or nurse you visit that you are using PTU.</li> <li>• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking PTU.</li> <li>• If you become pregnant while taking PTU, tell your doctor immediately.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take PTU to treat any other complaints unless your doctor tells you to.</li> <li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li> <li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how PTU affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 30°C. Keep your tablets in the bottle until it is time to take them.</li> <li>• Do not store PTU or any other medicine in the bathroom or near a sink.</li> <li>• Do not leave it on a window sill or in the car. Keep it where children cannot reach it.</li> </ul>

For more information, see Section [5. What should I know while using PTU™ 50 mg Tablets?](#) in the full CMI.

### 6. Are there any side effects?

**Common side effects** include itching, dizziness, joint pain, taste loss, nausea, vomiting, stomach pain, numbness or tingling of fingers, toes, or face, skin rash, skin or hair colour change, hair loss and sore, red or watery eyes. **Serious side effects** include yellow eyes and skin, hearing loss, swollen glands, unusual bleeding or bruising, increase or decrease in urination, backache, feet or lower legs swelling, joint pain, fever, skin rash or raised red lumps, wheezing or difficulty breathing, difficulty passing urine, hives, upper abdominal pain, tingling or pricking feeling, mouth ulcers and bleeding or bruising more easily than normal.

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.

# PTU™ 50 mg Tablets

Active ingredient: *Propylthiouracil*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PTU. **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 PTU.**

### Where to find information in this leaflet:

1. [Why am I using PTU™ 50 mg Tablets?](#)
2. [What should I know before I use PTU™ 50 mg Tablets?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use PTU™ 50 mg Tablets?](#)
5. [What should I know while using PTU™ 50 mg Tablets?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using PTU™ 50 mg Tablets?

**PTU contains the active ingredient propylthiouracil.** PTU belongs to a group of medicines called antithyroid medicines

**PTU is used to treat an overactive thyroid gland.**

An overactive thyroid gland produces too much thyroid hormones, also known as hyperthyroidism. This medicine may also be used to treat symptoms of hyperthyroidism before surgery or radioactive iodine therapy.

This medicine works by stopping thyroid hormone from forming. This medicine may take up to a week to reduce the symptoms of hyperthyroidism.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

## 2. What should I know before I use PTU™ 50 mg Tablets?

### Warnings

#### Do not use PTU if:

- you are allergic to propylthiouracil, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other similar medicines called thioamide derivatives.

### Check with your doctor if you have or have had:

- asthma
- allergies to any other medicines, foods, preservatives, or dyes

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.

PTU has caused, is suspected to have caused or may be expected to cause an increased incidence of human fetal malformations or irreversible damage.

Do not breastfeed if you are taking this medicine.

Talk to your doctor if you are breastfeeding or intend to breastfeed. The active ingredient in PTU passes into breast milk and there is a possibility that your baby may be affected.

## 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 PTU and affect how it works.

These include:

- medicines used to prevent blood clots or thin the blood, for example, heparin, warfarin, aspirin
- any medications which have a side effect called agranulocytosis, a lack of white blood cells. These include sulfonamide antibiotics, clozapine (a medicine used to treat schizophrenia) and spironolactone (a medicine used to treat hypertension). Ask your doctor for more information on the medicines that cause this side effect.

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

## 4. How do I use PTU™ 50 mg Tablets?

### How much to take

- Your doctor will tell you how many tablets to take, and when to take them each day.

- Follow the instructions provided and use PTU until your doctor tells you to stop.
- If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

### When to take PTU™ 50 mg Tablets

- PTU must be taken every day in equal doses at equal intervals during the day. If your doctor tells you to take 2 doses per day you would take each dose 12 hours apart. If your doctor tells you to take 4 doses per day you would take each dose 6 hours apart.
- Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- Continue taking your medicine for as long as your doctor tells you to.

### How to take PTU™ 50 mg Tablets

Swallow the tablets whole with a full glass of water.

### If you forget to use PTU™ 50 mg Tablets

**If it is less than 6 hours for a twice-daily dose or 3 hours for a four times daily dose before your next dose, skip the dose you missed and take your next dose when you are meant to.**

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

**Do not take a double dose to make up for the dose you missed.**

If you have trouble remembering to take your medicine or not sure what to do, ask your doctor or pharmacist for some hints.

### If you use too much PTU™ 50 mg Tablets

If you think that you have used too much PTU, 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 PTU™ 50 mg Tablets?

### Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking PTU.

Tell any other doctors, dentists, pharmacists and nurses who treat you that you are taking PTU.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking PTU. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking PTU.

### Call your doctor straight away if you:

- become pregnant during the course of PTU treatment.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using PTU.

### Things you should not do

- Do not stop using this medicine suddenly.
- Do not take PTU to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how PTU affects you.**

PTU may cause dizziness and/or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### Things to be careful of

Children should be careful when riding bicycles or climbing trees.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

### Looking after your medicine

- Keep your tablets in the bottle until it is time to take them.
- Store below 30°C.

Follow the instructions on the bottle on how to take care of your medicine properly.

Store it 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.**

### When to discard your medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

### 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<b>Eye related:</b> <ul style="list-style-type: none"> <li>• Sore, red, watery eyes</li> </ul> <b>Gastrointestinal:</b> <ul style="list-style-type: none"> <li>• nausea</li> <li>• stomach pain</li> <li>• vomiting</li> </ul> <b>Mouth related:</b> <ul style="list-style-type: none"> <li>• taste loss</li> </ul> <b>Musculoskeletal:</b> <ul style="list-style-type: none"> <li>• joint pain</li> </ul> <b>Nervous system:</b> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• numbness or tingling of fingers, toes, or face</li> </ul> <b>Skin related:</b> <ul style="list-style-type: none"> <li>• change in skin or hair colour</li> <li>• itching</li> <li>• hair loss</li> <li>• skin rash</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Less serious side effects (meaning PTU is not working the way it should)

Less serious side effects	What to do
<b>Infection:</b> <ul style="list-style-type: none"> <li>• fever</li> </ul> <b>Gastrointestinal:</b> <ul style="list-style-type: none"> <li>• diarrhoea</li> <li>• vomiting</li> </ul> <b>Nervous system:</b> <ul style="list-style-type: none"> <li>• irritability</li> </ul>	<b>Speak to your doctor as soon as possible if you have any of these less serious side effects and they worry you.</b>

<ul style="list-style-type: none"> <li>• listlessness</li> <li>• weakness</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<b>Eye related:</b> <ul style="list-style-type: none"> <li>• yellowing of the eyes</li> </ul> <b>Gastrointestinal:</b> <ul style="list-style-type: none"> <li>• constipation</li> <li>• nausea</li> <li>• upper stomach discomfort</li> <li>• upper abdominal pain</li> <li>• vomiting together with weight loss</li> </ul> <b>Heart-related:</b> <ul style="list-style-type: none"> <li>• slow heart rate</li> </ul> <b>Infection:</b> <ul style="list-style-type: none"> <li>• chills</li> <li>• fever</li> <li>• swollen glands</li> </ul> <b>Mouth related:</b> <ul style="list-style-type: none"> <li>• a deep and husky voice</li> <li>• mouth ulcers</li> </ul> <b>Musculoskeletal:</b> <ul style="list-style-type: none"> <li>• backache</li> <li>• muscle weakness, cramps</li> <li>• painful joints</li> <li>• swelling of feet or lower legs</li> <li>• unusual weight gain</li> </ul> <b>Nervous system related:</b> <ul style="list-style-type: none"> <li>• feeling cold</li> <li>• headache</li> <li>• lethargy</li> <li>• listlessness</li> <li>• tingling or pricking feeling</li> <li>• tiredness</li> </ul> <b>Renal system:</b> <ul style="list-style-type: none"> <li>• kidney disease</li> </ul> <b>Reproductive system:</b> <ul style="list-style-type: none"> <li>• change in menstrual periods</li> </ul> <b>Respiratory:</b> <ul style="list-style-type: none"> <li>• sore throat</li> <li>• wheezing or difficulty breathing</li> </ul> <b>Skin related:</b> <ul style="list-style-type: none"> <li>• dry, puffy, flaky skin</li> <li>• hair loss</li> <li>• hives</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

<ul style="list-style-type: none"> <li>• severe flaking or peeling of the skin</li> <li>• skin rash or red lumps</li> <li>• serious skin reactions and skin loss</li> <li>• bleeding or bruising</li> <li>• yellowing of the skin</li> </ul> <p><b>Urinary tract:</b></p> <ul style="list-style-type: none"> <li>• increase or decrease in urination</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### 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](http://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 PTU™ 50 mg Tablet contains

<b>Active ingredient (main ingredient)</b>	propylthiouracil
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate magnesium stearate maize starch povidone sodium lauryl sulfate

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

### What PTU™ 50 mg Tablet looks like

PTU tablet is round, white and biconvex. One side is debossed with "PRESTAB" while the other side is plain (AUST R 13319).

### Who distributes PTU™ 50 mg Tablets

PTU is supplied in Australia by:

Phebra Pty Ltd

19 Orion Road, Lane Cove West,

NSW 2066, Australia

Telephone: 1800 720 020

This leaflet was prepared in July 2021.

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