

PTU™ 50mg Tablets

Propylthiouracil

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about PTU. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking PTU against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What PTU is used for

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

This medicine belongs to a group of medicines called antithyroid medicines.

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.

Before you take PTU

When you must not take it

Do not take PTU if you have an allergy to:

- any medicine containing propylthiouracil
- any of the ingredients listed at the end of this leaflet
- any other similar medicines called thioamide derivatives.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not breast-feed if you are taking this medicine.

The active ingredient in PTU passes into breast milk and there is a possibility that your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had asthma.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking PTU.

Taking other medicines

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

Some medicines and PTU may interfere with each other. 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:
 - sulphonamide antibiotics
 - clozapine, a medicine used to treat schizophrenia
 - spironolactone, a medicine used to treat hypertension.

Ask your doctor for more information on medicines that cause this side effect.

These medicines may be affected by PTU or may affect how well it

works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take PTU

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How much to take

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

This will depend on your condition, what other medicines you are taking, and how you respond to treatment with PTU.

When your condition has improved your doctor may put you on a lower dose long term to maintain your condition.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

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.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

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 that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much PTU. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- symptoms of agranulocytosis:
 - mouth ulcers
 - sore throat
 - frequent infections such as fever, chills
 - headache, tiredness and lethargy.
- symptoms of hypothyroidism:
 - tiredness, lethargy

- muscle weakness, cramps
- feeling cold
- a slow heart rate
- dry, puffy, flaky skin
- hair loss
- a deep and husky voice
- unusual weight gain
- change in menstrual periods
- listlessness
- constipation
- headache.

While you are using PTU

Things you must 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, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests such as regular full blood counts, regular thyroid function tests and liver function tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

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.

If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Be careful driving or operating machinery until you know how PTU affects you.

This medicine 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. 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.

Standing up slowly, especially when you get up from bed or a chair, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking PTU.

This medicine helps most people with hyperthyroidism but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are a woman under 30 years of age you may have an increased chance of getting certain side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you (Those

indicating need for medical attention only if they continue or are bothersome):

- itching
- dizziness
- joint pain
- loss of taste
- nausea, vomiting, stomach pain
- numbness or tingling of fingers, toes, or face
- skin rash
- change in skin or hair colour, loss of hair
- sore, red, watery eyes.

The above list includes the side effects of your medicine that are usually mild and short-lived.

Tell your doctor as soon as possible if you notice the following symptoms of thyrotoxicosis (excess thyroid hormone):

- diarrhoea
- fever
- irritability, listlessness, weakness
- rapid or irregular heart beat
- vomiting.

The above list includes side effects, which could mean the medicine is not working properly.

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of the eyes and skin
- loss of hearing
- swollen glands
- unusual bleeding or bruising
- increase or decrease in urination
- backache
- swelling of feet or lower legssymptoms of vasculitis:
 - painful joints
 - fever
 - skin rash or raised red lumps
 - wheezing or difficulty breathing
 - difficulty passing urine
- hives
- upper abdominal pain
- tingling or pricking feeling.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to the Emergency Department at your nearest hospital:

- symptoms of agranulocytosis, granulocytopenia and leucopenia (lack of white blood cells):
 - mouth ulcers
 - sore throat
 - frequent infections such as fever, chills
 - headache, tiredness and lethargy
- symptoms of thrombocytopenia:
 - bleeding or bruising more easily than normal
- symptoms of hypothyroidism:
 - tiredness, lethargy
 - muscle weakness, cramps
 - feeling cold
 - a slow heart rate
 - dry, puffy, flaky skin
 - hair loss
 - a deep and husky voice
 - unusual weight gain
 - change in menstrual periods
 - listlessness
 - constipation
 - headache
- symptoms of hypersensitivity reactions: serious skin reactions and skin loss (Stevens Johnson syndrome and toxic epidermal necrolysis)
- symptoms of hepatotoxicity:
 - discomfort in the upper stomach
 - fever
 - nausea and vomiting together with weight loss.
- kidney disease
- severe flaking or peeling of the skin
- swelling of the lungs causing difficulty breathing
- skin rash with red lumps.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

After using PTU

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store PTU or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one and a half metres above the ground is a good place to store medicines.

Disposal

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.

Product description

What it looks like

PTU tablets are round, white and biconvex. One side is debossed with "PRESTAB" while the other side is plain.

PTU tablets are available in an amber glass bottle containing 100 tablets.

Ingredients

Each PTU tablet contains 50 mg of propylthiouracil as the active ingredient.

It also contains:

- lactose
- maize starch
- povidone
- methylated spirit (removed in process)
- sodium lauryl sulfate
- magnesium stearate.

This medicine does not contain sucrose, gluten, tartrazine dyes or preservatives.

Supplier

PTU is supplied in Australia by:

**Phebra Pty Ltd
19 Orion Road, Lane Cove West,
NSW 2066, Australia.
Telephone: 1800 720 020**

PTU is distributed in New Zealand by:

**AFT Pharmaceuticals Ltd
PO Box 33-203, Auckland.
Telephone: +64 9 4880232**

PTU™ 50 mg Tablets
100 tablets per bottle

AUST R 13319

Phebra Product Code- TAB001

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