

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **PROPYLTHIOURACIL TABLETS**

Read this carefully before you start taking **PROPYLTHIOURACIL TABLETS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PROPYLTHIOURACIL TABLETS**.

Serious Warnings and Precautions

- **Agranulocytosis (low white blood cells):** Treatment with **PROPYLTHIOURACIL TABLETS** can cause agranulocytosis, especially during the initial three months of treatment. This can lead to serious complications or even death. The symptoms can include unusual bleeding, fever, sore throat, bruising, or skin rashes. Your healthcare professional will monitor your health throughout your treatment. However, if you notice any of these symptoms tell your healthcare professional right away. They will stop your treatment if agranulocytosis is suspected.
- **Liver problems:** Treatment with **PROPYLTHIOURACIL TABLETS** can cause liver injury leading to liver problems, liver failure, or death. This usually occurs during the initial two months of treatment. The symptoms can include: anorexia, itchiness, yellowing of the eyes or skin, light coloured stools, dark urine, and abdominal pain. If these occur your healthcare professional will assess your liver and may decide to stop your treatment.

What is **PROPYLTHIOURACIL TABLETS** used for?

PROPYLTHIOURACIL TABLETS is used in adults:

- to treat hyperthyroidism (overactive thyroid gland);
- to speed up recovery when used in combination with radioactive iodine therapy;
- to control symptoms of hyperthyroidism before a surgery; and
- to manage symptoms of a thyroid storm (thyroid gland produces too much thyroid hormone in a short period of time).

How does **PROPYLTHIOURACIL TABLETS** work?

PROPYLTHIOURACIL TABLETS belongs to a group of medications called antithyroid medicines. It works by stopping the thyroid gland from making thyroid hormones. This medication may take a few weeks to reduce the symptoms of hyperthyroidism.

What are the ingredients in **PROPYLTHIOURACIL TABLETS**?

Medicinal ingredient: propylthiouracil.

Non-medicinal ingredients: lactose monohydrate, magnesium stearate, maize starch, povidone and sodium lauryl sulfate.

PROPYLTHIOURACIL TABLETS comes in the following dosage forms:

Tablets: 50 mg of propylthiouracil.

Do not use PROPYLTHIOURACIL TABLETS if:

- you are allergic to propylthiouracil or any of the other ingredients in PROPYLTHIOURACIL TABLETS;
- you are allergic to similar antithyroid medications known as thioamide derivatives. Ask your healthcare professional if you are unsure;
- you are breastfeeding or planning to breastfeed.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PROPYLTHIOURACIL TABLETS. Talk about any health conditions or problems you may have, including if you:

- have a low white blood cell count;
- have joint pain;
- have asthma;
- have skin problems;
- have or have had liver problems;
- are taking medications known to be associated with agranulocytosis (ask your healthcare professional if you are unsure);
- have inflamed blood vessels (vasculitis);
- have or have had kidney problems;
- are intolerant to some sugars (e.g., lactose, a milk sugar which is a component of PROPYLTHIOURACIL TABLETS);
- are taking anticoagulant (medications used to prevent your blood from clotting);
- are planning to have a surgery;
- are pregnant, think you may be pregnant, or plan to become pregnant.

Other warnings you should know about:

- **Vasculitis (inflammation of the blood vessel):** Treatment with PROPYLTHIOURACIL TABLETS can cause vasculitis, which can lead to severe organ damage or death. This can occur to the blood vessels in your kidneys, skin, lungs, brain, and intestine. The symptoms of vasculitis include blood in your urine, less urine, a new rash, shortness of breath, or coughing up blood. If you notice any of these symptoms tell your healthcare professional. They may discontinue your treatment and may initiate the appropriate intervention.
- **Hypothyroidism (thyroid gland is producing not enough thyroid hormone):** Treatment with PROPYLTHIOURACIL TABLETS can cause hypothyroidism. The symptoms can include weight gain, tiredness, hair loss, muscle weakness, feeling cold, dry skin, constipation, puffy face, heavier than normal or irregular menstrual periods, and enlarged thyroid gland. If signs of hypothyroidism occur, tell your healthcare professional. They may reduce or temporarily stop your treatment, and may also perform tests to measure your hormone levels.

- **Skin rashes:** Treatment with PROPYLTHIOURACIL TABLETS can cause skin rashes. This can be a sign of an allergic reaction or a skin reaction (e.g., Stevens-Johnson syndrome or toxic epidermal necrolysis). If you notice a skin rash stop taking PROPYLTHIOURACIL TABLETS right away and tell your healthcare professional.
- **Blood problems:** Treatment with PROPYLTHIOURACIL TABLETS can cause decreased levels of red blood cells, white blood cells, and/or blood platelets. Your healthcare professional may do blood tests to monitor the profile of your blood. They may decide to reduce or stop your dose of PROPYLTHIOURACIL TABLETS.

See the **Serious side effects and what to do about them table**, below, for more information on these and other serious side effects.

Monitoring and Testing:

Your healthcare professional will monitor your health which can include doing blood tests. These tests may be performed before and periodically during your treatment to assess the functions of your liver, thyroid, blood, and blood clotting. This will tell your healthcare professional how PROPYLTHIOURACIL TABLETS is affecting you.

Pregnancy:

- If you are pregnant or are able to become pregnant, there are specific risks for you and your unborn baby that you must discuss with your healthcare professional.
- If you are prescribed PROPYLTHIOURACIL TABLETS while you are pregnant, your healthcare professional will also closely monitor you and your unborn baby to ensure that PROPYLTHIOURACIL TABLETS is working correctly. They may also switch your treatment after the first trimester of your pregnancy.
- You should use effective birth control while taking PROPYLTHIOURACIL TABLETS to avoid potential risks.
- If you become pregnant or think you are pregnant while taking PROPYLTHIOURACIL TABLETS, tell your healthcare professional right away.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PROPYLTHIOURACIL TABLETS:

- medicines that might need a reduced dose when hyperthyroid patients become euthyroid such as:
 - theophylline, a drug used to treat asthma;
 - digoxin, used to treat problems with the rhythm of your heart;
 - beta blockers, used to treat high blood pressure.

You should not take PROPYLTHIOURACIL TABLETS before you have radio-iodine (¹³¹I) therapy for an overactive thyroid gland (hyperthyroidism) because it can reduce the effectiveness of radio-iodine (¹³¹I) therapy.

Serious Drug Interactions

- Taking PROPYLTHIOURACIL TABLETS with anticoagulants (medicines used to prevent blood clots or thin the blood such as warfarin or heparin), can increase your risk of hypoprothrombinemia (low prothrombin, a blood clotting substance). Ask your healthcare professional if you are unsure.
- Taking PROPYLTHIOURACIL TABLETS with any medications that may lead to agranulocytosis (low white blood cells) may increase your risk of agranulocytosis. Ask your healthcare professional if you are unsure.

How to take PROPYLTHIOURACIL TABLETS:

- You can take PROPYLTHIOURACIL TABLETS with or without food.
- Swallow the tablets whole with a drink of water. Do not chew, split or crush tablets. If the tablet is broken, cracked, or otherwise not intact, do not take the tablet.

Usual dose:

Your healthcare professional 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 PROPYLTHIOURACIL TABLETS.

When your condition has improved your healthcare professional may put you on a lower dose to maintain your condition.

Overdose:

You may need urgent medical attention in the case of an overdose. An overdose can lead to the following:

- agranulocytosis (low white blood cells);
- hypothyroidism (thyroid gland is producing not enough thyroid hormone);
- haemorrhage (blood loss);
- Henoch-Schonlein purpura (HSP; inflammation of the small blood vessels).

If you think you, or a person you are caring for, have taken too much PROPYLTHIOURACIL TABLETS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

The actions for a missed dose differ depending on how many tablets you are prescribed to take each day:

- **Two times a day:** If it is less than 6 hours before your next dose, skip the dose you missed, and take the next dose at the scheduled time. If it is more than 6 hours before your next dose, take the missed dose as soon as you remember, and then go back to taking your medicine as you would normally.
- **Four times a day:** If it is less than 3 hours before your next dose, skip the dose and take the next dose at the scheduled time. If it is more than 3 hours before your next dose, take the missed dose as soon as you remember, and then go back to taking your medicine as you would normally.

In both cases, do not try to make up for a missed dose by taking a double dose. This may increase the chances of you getting an unwanted side effect. If you are not sure what to do, ask your healthcare professional.

What are possible side effects from using PROPYLTHIOURACIL TABLETS?

These are not all the possible side effects you may have when taking PROPYLTHIOURACIL TABLETS. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- abdominal discomfort;
- back pain;
- drowsiness;
- burning or prickling sensation in the hands, arms, legs, or feet;
- loss of taste;
- hair loss;
- change in hair colour.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Liver problems (including inflammation or damage to the liver, and the death of liver cells): yellowing of the skin or eyes (jaundice), stomach pain or swelling, nausea, vomiting, unusual dark urine, unusual tiredness, fever, light-coloured stool, urine turns dark, and loss of appetite for several days or longer			√
Kidney problems (including kidney inflammation (nephritis)): blood in the urine, bruises and blood spots, breathlessness, coughing, swelling of your lymph glands (glands situated around the body which protect against the spread of infection), swelling of the blood			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
vessels in your skin, pain in your lower back / less oxygen to the body, development of anemia			
Agranulocytosis (low white blood cells): unusual bleeding, infections, fever, chills, sore throat, bruising, and skin rashes			√
RARE			
Aplastic anemia (when cells meant to develop into mature blood cells are damaged): fatigue, weakness, and pale skin			√
VERY RARE			
Vasculitis (inflammation of the blood vessels): blood in your urine, less urine, a new rash, shortness of breath, coughing up blood, fever, fatigue, weight loss, and general aches or pains			√
Leukopenia (low white blood cells): infections, fatigue, fever, aches, pains, and flu-like symptoms			√
Thrombocytopenia (low blood platelets): bruising or bleeding for longer than usual if you hurt yourself, fatigue, and weakness			√
Hypothyroidism (thyroid gland is producing not enough thyroid hormone): 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, and puffy face			√
Allergic reactions (including Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)): fever, skin rash, hives, itching, swelling, shortness of breath, wheezing, runny nose, itchy, watery eyes, redness, blistering and/or peeling of the skin and/or inside of the lips, eyes, mouth, nasal passages or genitals, chills, headache, cough, body aches or swollen glands, and redness			√
Encephalopathy (a disease that affects the function or structure of the brain): loss of memory, cognitive impairment, personality changes, inability to concentrate, laziness, coordination or balance problems, muscle twitches, sleep problems, and slurred speech			√
Anemia (low red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, and weakness			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Hemolytic anemia (breakdown of red blood cells): pale skin, feeling tired or weak, dizziness, fainting, thirst, and rapid breathing			√
Hypoprothrombinemia (low prothrombin, a blood clotting substance): bleeding or bruising easily, blood in stool, blood in urine, gums bleed easily, nosebleeds, and swelling or pain your joints			√
Myeloblastic leukemia (a type of cancer of the blood and bone marrow): pale skin, tiredness, breathlessness, high body temperature, feeling hot, sweating, weight loss, unusual bleeding, bruising easily, red or purple spots on the skin, bone or joint pain, stomach discomfort, and swollen glands in your neck, armpit or groin			√
Hyperglobulinemia (high globulins in the blood): fatigue, weakness, dizziness, confusion, muscle numbness, tingling, loss of appetite, weight loss, fever, abnormal bleeding, and headaches			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store PROPYLTHIOURACIL TABLETS at room temperature (15°C to 30°C).

Keep out of reach and sight of children.

If you want more information about PROPYLTHIOURACIL TABLETS:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.phebra.com/cae, or by calling 1-866-333-5458.

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