PACKAGE LEAFLET: INFORMATION FOR THE USER

Propylthiouracil 50 mg Tablets

propylthiouracil

Area reserved for Pharmacode

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Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others as it may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Propylthiouracil 50 mg Tablets are called 'Propylthiouracil Tablets' in this leaflet.

What is in this leaflet

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2. What you need to know before you take Propylthiouracil Tablets
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1. What Propylthiouracil Tablets are and what they are used for

Propylthiouracil Tablets contains the active substance propylthiouracil.

Propylthiouracil is used to treat hyperthyroidism in adults (including the elderly) and in children and adolescents aged 6 to 18 years. Hyperthyroidism is a condition where the thyroid gland is overactive and makes too much thyroid hormone called thyroxine. Thyroxine helps to regulate the body's growth and metabolism.

This medicine helps restore thyroxine levels in your bloodstream to normal levels: It may take several weeks for this to happen. Hence it is important to keep taking the medicine every day.

2. What you need to know before you take Propylthiouracil Tablets

Do not take Propylthiouracil Tablets:

- if you are allergic to propylthiouracil or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Propylthiouracil:

- if you are prone to getting infections.

- if you have or have ever had liver or kidney problems.

Talk to your doctor or pharmacist immediately if during treatment you suffer from:

- a sore throat, fever, mouth ulcers or other symptoms of infection because propylthiouracil may affect your body's ability to fight an infection.
- liver problems or the side effects of liver problems such as anorexia, itching or pain in the upper part of your stomach on the right side.
- kidney problems.

Your doctor will arrange for you to have regular blood tests to make sure that the medicine is working properly.

Check with your doctor if any of the following applies to you:

- If you have, or have ever had, liver or kidney problems

Severe liver reactions, including those that mean you need to have a liver transplant, or which could be fatal, have been reported in children and adults treated with propylthiouracil.

Tell your doctor immediately if you develop symptoms of liver disease, such as feeling sick or being sick, diarrhoea, yellowing of your skin and the whites of your eyes (jaundice), dark pee, pale poo, bleeding easily, itching or chills.

If any of the above applies to you, tell your doctor before you start taking propylthiouracil tablets.

Other medicines and Propylthiouracil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take, any other medicines, including:

- Theophylline, a drug used to treat asthma.
- Digoxin, a drug used to treat problems with the rhythm of your heart
- Beta-blockers, used to treat high blood pressure

Propylthiouracil can affect how these, or other medicines, work. Your doctor may need to change how much of these medicines you need to take.

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Some studies suggest there may be a slight increased risk of birth defects in babies born to women with hyperthyroidism who were treated with Propylthiouracil Tablets during pregnancy, when compared with babies born to women who do not have hyperthyroidism, while others do not suggest an increased risk. The risk is not higher than the risk in babies born to women with untreated overt hyperthyroidism during pregnancy. If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor straight away. You may need treatment with Propylthiouracil Tablets during pregnancy if your doctor thinks that the benefit of taking it outweighs the risk to you and your unborn baby. However it may affect your unborn baby.

If you need to take Propylthiouracil Tablets during pregnancy, your doctor will give you the lowest possible dose and your thyroid function will be tested regularly (usually every four to six weeks).

Breast-feeding

Tell your doctor if you are breast-feeding or want to start breast-feeding while you are taking Propylthiouracil Tablets. Propylthiouracil passes into breast milk and may affect your child's development. If you need to take Propylthiouracil Tablets while you are breast-feeding, your doctor will give you the lowest possible dose and your baby's development will be closely monitored.

Fertility

If you suffer from hyperthyroidism this may affect your fertility. Taking Propylthiouracil Tablets can restore your fertility to normal levels.

Driving and using machines

Propylthiouracil Tablets should not affect your ability to drive or use machines.

Propylthiouracil Tablets contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Propylthiouracil Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Propylthiouracil Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The dose will be on the pharmacist's label. It should tell you how many tablets to take and how often. Also follow any special instructions or warnings which appear on the pharmacist's label.

You can take Propylthiouracil Tablets with or without food. Swallow the tablets whole with a drink of water. Unless your doctor has told you otherwise, try to take the tablets at the same time each day. This will help you to remember to take them.

Adults, including the elderly

The usual starting dose is 300 to 600 mg daily (6 to 12 tablets), taken as recommended by your doctor. When your condition has been controlled (usually after one to two months) the dose is usually reduced to 50 to 150 mg daily (1 to 3 tablets) and continued for one to two years.

Use in children and adolescents

Children aged ten years and above

The usual starting dose is 150 mg to 300 mg (3 to 6 tablets) once daily or in divided doses.

Children aged six to ten years

The usual starting dose is 50 to 150 mg (1 to 3 tablets) once daily or in divided doses.

Children under six years

Do not give this medicine to children under six years because it is unlikely to be safe.

Kidney or liver disease

If you have kidney or liver disease your doctor will adjust your dose according to your condition.

If you take more Propylthiouracil Tablets than you should

If you accidentally take too many tablets contact your doctor or pharmacist or nearest hospital casualty department **immediately**. Take this leaflet and any remaining tablets with you to show the doctor or pharmacist.

Signs that you have taken too many tablets include being sick, stomach pain, headache, fever, joint pain, itching, being pale, tiredness, frequent infections, unusual bleeding or unexplained bruising.

If you take too high a dose over a period of time this can cause a swelling of your thyroid gland (at the front of your neck. Your thyroid gland may become underactive, in which case you may feel tired or cold or put on weight.

If you forget to take Propylthiouracil Tablets

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the missed dose at all: do not take a double dose to make up for a forgotten tablet.

If you stop taking Propylthiouracil Tablets

You should continue to take your medicine for as long as your doctor tells you. Do not stop taking the medicine without first talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, particularly when treatment is first started, although not everybody gets them.

Stop taking Propylthiouracil Tablets and contact your doctor or the nearest hospital accident and emergency department immediately if you experience any of these side effects while taking Propylthiouracil Tablets:

Symptoms of an allergic reaction:

- difficulty in breathing
- cough
- swelling of your lymph glands (glands situated around the body which protect against the spread of infection)
- arthritis (painful joints)
- pain in your lower back or other symptoms of kidney problems
- inflammation of your blood vessels (of the skin)
- a rash across the bridge of your nose and across your cheeks

Symptoms of liver problems (including inflammation of your liver (hepatitis), liver failure or other forms of liver damage (some of which can cause death):

- yellowing of the skin and whites of the eyes (jaundice)
- pain on the right side of your stomach
- itching
- loss of appetite

- a brain disease which may affect your ability to think

Severe liver reactions, including those with a fatal outcome, or which require a liver transplant, have been reported in both children and adults taking propylthiouracil.

Symptoms of kidney problems, including inflamed kidneys (nephritis):

- blood in your urine
- bruises and blood spots
- shortness of breath
- coughing
- swollen lymph glands (the glands situated around your body which protect you against the spread of infection)
- swollen blood vessels under your skin
- pain in your lower back

Symptoms of a serious problem affecting your blood:

- sore throat
- fever
- mouth ulcers
- unusual bleeding or unexplained bruising
- unusual tiredness or weakness
- feeling generally unwell

You should contact your doctor immediately if you develop any of these side effects.

Other less serious side effects include:

Very Common (≥1/10)

- itchy or reddened skin
- fever

Common (≥1/100, <1/10)

- lower than normal levels of white blood cells
- stomach upset
- feeling sick or being sick
- change in the way things taste
- skin rashes
- abnormal results of liver function tests

Uncommon (≥1/1000, <1/100)

- problems with your body making the right blood cells, which can make you at risk of getting an infection
- bleeding because you do not have enough of the cells that help your blood clot
- headache
- inflammation of your blood vessels
- stomach pain
- liver problems (see above)

Rare (≥1/10,000, <1/1,000)

- lack of a blood clotting factor
- swollen lymph glands (see above)
- low blood cell count
- dizziness
- tingling or "pins and needles" under your skin
- hearing loss
- inflammation of your arteries
- inflammation of your lungs
- Yellowing of your skin and whites of your eyes caused by a liver problem (see above)
- an extreme reaction to the drug which damages your blood vessels
- hair loss
- a long-term condition that causes joint pain, skin rashes and tiredness, known as 'Lupus'
- back ache
- problems with your muscles caused by your nerves
- swollen ankles, feet and legs

Very rare (<1/10,000)

- problems with your body making and looking after your red blood cells
- asthma
- pain or stiffness in your muscles or joints
- acute kidney failure (see above)

Frequency is not known.

- being very sensitive to something that gives you an allergy (hypersensitivity)
- muscle weakness
- bleeding in the lung
- infection in your salivary gland(s)
- liver failure (see above)
- changes in the colour of your skin
- muscle weakness
- swelling
- a problem with your antibodies that affects white blood cells

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to HPRA Pharmacovigilance. Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Propylthiouracil Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the outer carton, bottle label or blister pack after EXP. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. This medicine does not require any special temperature storage conditions

Do not use this medicine if you notice visible signs of deterioration such as discoloration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Propylthiouracil Tablets contains

The active substance is propylthiouracil. Each tablet contains 50 mg of propylthiouracil.

The other ingredients are lactose monohydrate, acacia (spray-dried), croscarmellose sodium, sodium laurilsulfate and magnesium stearate.

What Propylthiouracil Tablets looks like and contents of the pack

Propylthiouracil Tablets are white, circular, biconvex tablets of approximately 6.5 mm by 3 mm.

Propylthiouracil Tablets are available in plastic (polypropylene) bottles of 100 tablets and blister packs of 28 tablets, 56 tablets or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Halewood Pharma Limited, Unit 3D North Point House, North Point Business Park, New Mallow Road, Cork, T23 WYK5, Republic of Ireland

Manufacturer: Pharmadox Healthcare Ltd, KW20A Kordin Industrial Park, Paola PLA3000, Malta.

Manufacturer: Medinfar Manufacturing S.A., Parque Industrial Armando Martins Tavares, Rua Outeiro Da Armada No 5, Condeixa-A-Nova, 3150-194, Portugal

This leaflet was last revised in June 2026