

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).
- if you have ever had a severe allergic reaction to propylthiouracil, including a reduced white blood cell count, liver problems, inflamed blood vessels and kidney problems.

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.
- if you have a rare hereditary condition such as galactose intolerance, the Lapp lactase deficiency or are unable to absorb glucose-galactose you should not take this medicine.

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:

- Some cases of severe liver reactions, including cases with fatal outcome or requiring liver transplant, have been reported in both children and adults treated with propylthiouracil. You should inform your doctor immediately if you develop symptoms of liver disease, such as nausea, feeling sick, diarrhoea, yellow discolouration of the skin or eyes, dark urine, pale stools, bleeding easily, itching or chills.
- If you have liver or kidney problems

If any of the above applies to you, you should speak to your doctor before 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, used to treat problems with the rhythm of your heart
- Beta-blockers, used to treat high blood pressure

Propylthiouracil can affect how these medicines 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 (¹³¹I) therapy for an overactive thyroid gland (hyperthyroidism) because it can reduce the effectiveness of radio-iodine (¹³¹I) 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

The potential of Propylthiouracil Tablets to cause harm to an unborn baby is uncertain.

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 the potential benefit outweighs the potential risk to you and your unborn baby.

Propylthiouracil Tablets may be taken during pregnancy but it may affect your unborn baby. If you need to take Propylthiouracil Tablets during pregnancy, you should be given the lowest possible dose and your thyroid function should be tested every four to six weeks.

Breast-feeding

You should tell your doctor if you are breast-feeding or wish to start breast-feeding whilst taking Propylthiouracil Tablets. Propylthiouracil passes into breast milk and may affect your child's development. If you need to take Propylthiouracil Tablets whilst you are breast-feeding, you should be given the lowest possible dose and your baby's development should 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 recommended 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 over ten years

The recommended starting dose is 150 to 300 mg daily (3 to 6 tablets), taken as recommended by your doctor.

Children aged six to ten years

The recommended starting dose is 50 to 150 mg daily (1 to 3 tablets), taken as recommended by your doctor.

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 reduce 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, then 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 talking to your doctor first.

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 whilst 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

Some cases of severe liver reactions, including cases with fatal outcome or requiring liver transplant, have been reported in both children and adults treated with propylthiouracil.

Symptoms of 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 vessels in 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:

- feeling sick or being sick
- stomach upsets
- taste disturbance
- headaches
- hearing loss
- mild skin rashes
- itching or reddening of the skin
- hair loss
- pain or stiffness of your muscles or joints
- abnormal results of liver function tests

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 via the national reporting systems below:

United Kingdom: Yellow card scheme: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2. Tel: +353 1 6764971

Fax: +353 1 6762517. Website: www.hpra.ie. Email: medsafety@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:

UK: Halewood Chemicals Ltd, The Mill, Horton Road, Stanwell Moor, Staines, Middlesex, TW19 6BJ, UK.

Ireland: Halewood Chemicals (Ireland) Ltd, Unit 3D North Point House, North Point Business Park, New Mallow Road, Cork, Republic of Ireland

Manufacturer: Surepharm Services Limited, Unit 2B Bretby Business Park, Ashby Road East Bretby, Burton on Trent, Staffordshire, DE15 0YZ, UK.

This leaflet was last revised in March 2023