

PACKAGE LEAFLET
INFORMATION FOR THE USER

Propylthiouracil 50mg Tablets (Propylthiouracil)



Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

The name of your medicine is Propylthiouracil 50mg Tablets. In the rest of this leaflet it is called Propylthiouracil Tablets.

In this leaflet:

1. What Propylthiouracil Tablets are and what they are used for
2. Before you take Propylthiouracil Tablets
3. How to take Propylthiouracil Tablets
4. Possible side effects
5. How to store Propylthiouracil Tablets
6. Further information

1. WHAT PROPYLTHIOURACIL TABLETS ARE AND WHAT THEY ARE USED FOR

The active ingredient in Propylthiouracil Tablets is propylthiouracil, which belongs to a group of medicines called antithyroid drugs. These medicines work by reducing the production of a hormone called thyroxine by the thyroid gland (a gland located beneath the box in the throat that produces thyroid hormone and helps to regulate growth and metabolism).

Propylthiouracil Tablets are used in the treatment and management of an overactive thyroid gland (hyperthyroidism).

2. BEFORE YOU TAKE PROPYLTHIOURACIL TABLETS

Do not take Propylthiouracil Tablets if you:

- are **severely allergic to propylthiouracil or any of the other ingredients of Propylthiouracil Tablets** (see section 6 'What Propylthiouracil Tablets contain' for a full list of ingredients).
- have a **rare hereditary condition** affecting the way your **body handles some sugars**

If any of the above apply to you, you should not take Propylthiouracil Tablets.

Propylthiouracil Tablets are not recommended for use in children under six years of age.

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.

Taking other medicines

Taking other medicine while you are taking Propylthiouracil Tablets can

affect how it or the medicine works. Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, including those you may have bought yourself without a prescription.

Please check with your doctor if you are taking any of the following (or any other medication):

- 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
- Radio-iodine, used to treat an overactive thyroid gland

If you have any doubts about whether you should take this medicine then discuss matters with your doctor before taking it.

Pregnancy and breast-feeding

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 child's thyroid gland. If you need to take Propylthiouracil Tablets during pregnancy, you should be given the lowest effective dose and your thyroid function should be checked every four to six weeks.

You should inform your doctor if you are breast-feeding or wish to start breast-feeding whilst taking Propylthiouracil Tablets. If you need to take Propylthiouracil Tablets whilst you are breast-feeding, you should be given the lowest effective dose and the infant's development and thyroid function should be monitored.

Driving and using machinery

Propylthiouracil Tablets are not known to affect the ability to drive or operate machinery.

Important information for patients who have an intolerance to some sugars

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product, as it contains lactose.

3. HOW TO TAKE PROPYLTHIOURACIL TABLETS

Your doctor will decide the dose which is best for you. Always follow your doctor's instructions completely and also follow any special instructions or warnings which appear on the label which the pharmacist has put on the package. If you do not understand, or are in any doubt, ask your doctor or pharmacist

Unless instructed differently, take your tablets with a glass of water.

Adults and the elderly

The usual adult starting dose for Propylthiouracil Tablets is 300 to 600mg once a day, or in divided doses, until your condition is controlled.

When your condition has been controlled (usually after one to two months) the dose is reduced to 50 to 150mg daily and continued for one to two years.

Propylthiouracil Tablets are not recommended for use in children under six years of age.

Children aged six to ten years of age

In children aged six to ten years, the usual starting dose is 50 to 150mg once daily or in divided doses.

Children over ten years of age

In children over ten years, the usual starting dose is 150 to 300mg once daily or in divided doses.

If you have kidney or liver disease

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

Laboratory tests

Your doctor will normally arrange for you to have regular blood tests to ensure Propylthiouracil Tablets are working properly.

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. Too high a dose over a period of time can cause a swelling of your thyroid (at the front of your neck) and your thyroid gland may become underactive in which case you may feel tired or cold or put on weight.

If you miss a dose of Propylthiouracil Tablets

If you forget to take a dose, take another 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 your forgotten tablet.

Stopping taking Propylthiouracil Tablets

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

4. POSSIBLE SIDE EFFECTS

Like many medicines Propylthiouracil Tablets may cause side effects in some patients, although not everybody gets them.

You should contact your doctor immediately if you develop any of the following side effects affecting your blood or liver, or if you think you have any type of infection:

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.

Your doctor should check your blood if you develop an infection or if you are about to undergo surgery. You may need to stop your tablets if you have any blood problems.

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

- loss of appetite
- itching
- pain on the right side of your stomach
- jaundice (yellowing of the skin and whites of the eyes)
- a brain disease, which may affect your ability to think

You should contact your doctor immediately if you develop any of the above side effects

You should also contact your doctor immediately if you develop an allergic reaction, the symptoms of which are as follows:

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 the loins (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

Other less serious side effects include:

- feeling sick or being sick
- stomach upsets
- taste disturbance
- headaches
- hearing impairment
- 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

Reporting of side effects

If you get any side effects, talk to your doctor, or 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 listed below:

United Kingdom:

Yellow Card Scheme

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

Malta:

ADR Reporting

Website:

www.medicinesauthority.gov.mt/adrportal

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

5. HOW TO STORE PROPYLTHIOURACIL TABLETS

Keep out of the sight and reach of children.

Do not take this medicine if the expiry date on the label has passed. The expiry date refers to the last day of that month.

Propylthiouracil Tablets should not be taken if they show signs of deterioration such as discoloration.

Do not store above 25°C.

Store in the original container or package in order to protect from light and moisture.

Do not transfer the tablets to another container.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Propylthiouracil Tablets contain

The active ingredient in Propylthiouracil Tablets is propylthiouracil.

The tablets are available in one strength of 50mg.

The other ingredients in your tablets are lactose, maize starch, pregelatinised maize starch, magnesium stearate and sodium starch glycollate.

What Propylthiouracil Tablets look like and contents of the pack

Propylthiouracil Tablets are white, circular tablets, rounded on both sides, with a breakline on one side and CP on the other.

Propylthiouracil Tablets are available in polypropylene or polyethylene (plastic) tablet containers of 56 or 100 tablets.

Marketing Authorisation Holder in UK: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Marketing Authorisation Holder in Malta: Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland
Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio, please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Reference number
Propylthiouracil 50mg Tablets	29831/0179

This is a service provided by the Royal National Institute of Blind People.

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