



PACKAGE LEAFLET: INFORMATION FOR THE USER

Propylthiouracil

50 mg and 100 mg Tablets

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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

The active ingredient in Propylthiouracil Tablets is propylthiouracil. Propylthiouracil Tablets are used in the treatment of hyperthyroidism. Hyperthyroidism is where an overactive thyroid gland produces too much thyroid hormone. They are also used to treat Graves' disease, thyrotoxicosis and thyrotoxic crisis (when levels of thyroid hormone are dangerously high). Propylthiouracil Tablets may also be given to lower very high levels of thyroid hormone before surgery or radioactive iodine treatment. Children may be given Propylthiouracil Tablets to delay the need for surgery (or other treatment to remove part of an overactive thyroid gland).

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 or pharmacist before taking Propylthiouracil Tablets if you:

- have ever had an adverse reaction to propylthiouracil or to any of the other ingredients of this medicine (listed in section 6.);
- are pregnant, may become pregnant or are breastfeeding;
- have ever had any problems with your liver or kidneys;
- are older than 40 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.

Other medicines and Propylthiouracil Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can interfere with your treatment. Tell your doctor if you are taking any of the following:

- Any mineral supplements in your diet which may contain iodine.

- Medicines which will reduce the number of white blood cells in your body and hence lower your resistance to infection. If you are not sure, you should ask your doctor or pharmacist who will be able to give you this information.
- Medicines containing theophylline, aminophylline or digoxin.
- Other medicines including ones that you have bought for yourself without a prescription.

Pregnancy and breast-feeding

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

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, tell your doctor or pharmacist for advice before taking this medicine. You may need treatment with Propylthiouracil Tablets during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.

Driving and using machines

Propylthiouracil has no documented effects on the ability to drive or use machines. However, if you feel drowsy or confused, you should not drive or operate machines.

Propylthiouracil Tablets contain lactose

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

Important information about Propylthiouracil Tablets

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

If you see another doctor or visit a hospital, remember to tell them what medicines you are already taking.

3. How to take Propylthiouracil Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take and how often. Your doctor may want you to have regular blood tests or other tests to check your condition and to make sure that you are taking the right dose. Swallow the tablets whole with water.

The following doses are intended as a guide:

Adults:

For management of hyperthyroidism and prior to surgery: the starting dose is between 300mg and 600mg a day, taken as a single dose or in divided doses. This may be gradually reduced to between 50mg and 150mg daily as your condition improves.

In preparation for radioactive iodine therapy: The dose is as above and should be taken for several weeks prior to radioactive iodine therapy. Treatment should be stopped 2 to 4 days before iodine treatment.

For thyrotoxic crisis: The dose is 200mg every 4 to 6 hours for the first 24 hours. This is then reduced as the condition improves. Elderly patients will be given the adult dose mentioned above. Patients with liver or kidney problems may be given a lower dose.

Children:

Aged 6 to 10 years: The starting dose is 50mg to 150mg a day.
Aged over 10 years: The starting dose is 150mg to 300mg a day.

Neonates (babies less than 4 weeks old): The dose will be worked out depending on the baby's weight. The usual daily dose is 5mg to 10mg for each kilogram of body weight.

If you forget to take Propylthiouracil Tablets

If you forget to take a dose at the right time, take it as soon as you remember. Do not take two doses together. If it is almost time to take the next dose, wait until then and then carry on as before.

If you take more Propylthiouracil Tablets than you should

It is important not to take too many tablets. Contact your nearest hospital casualty department or a doctor for advice if you have swallowed too many tablets or if you think a child has swallowed any. Take this leaflet, and any tablets that you still have to show the doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you get:

- A fever, sore throat, rashes or ulcers in your mouth and throat, as this could be a sign that you are not making any white blood cells to fight off infection. If this happens your treatment should be stopped. However this is a rare side effect and occurs most commonly within the first two months of treatment and in patients over the age of 40 who are taking larger doses.
- Fever, joint swelling and pain, muscle aches, blood in urine, shortness of breath, rash.

Propylthiouracil may cause the increase of a particular type of antibody “ANCA” (anti-neutrophil cytoplasmic antibodies) and inflammation of the walls of blood vessels which can be serious if not treated. This can occur even if you have been taking propylthiouracil for many years.

You should tell your doctor if you suffer from any of the following for more than a few days:

- Rash;
- Itching;
- Hair loss;
- Skin colourations;
- Swelling (for example in the legs and feet);
- Being and feeling sick;
- Stomach upset;
- Loss of taste;
- Muscle or joint pain;
- Pins and needles and headache.

Frequency unknown: Liver failure, liver inflammation.

Other rare side effects are:

- Anaemia, fever, weak and tender muscles, lupus-like syndrome (seen as a red, scaly rash on the nose and cheeks and/or stiffness in the joints and malaise);
- Liver damage or inflammation, which can include hepatitis, jaundice (yellow skin and whites of the eyes), confusion, coma and death;
- Kidney inflammation (blood in the urine), bruises and blood spots due to inflammation of the small blood vessels in the skin, breathlessness and cough;
- Slow blood clotting, bleeding and bruising more easily than usual.

If you feel unwell in any other way, tell your doctor as soon as you can.

Your body may make less white blood cells than normal which may make you more prone to picking up infections.

Levels will go back to normal when you stop taking your treatment.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme on the MHRA website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Propylthiouracil Tablets

This medicinal product does not require any special storage conditions.

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

Do not take this medicine after the expiry date which is stated on the carton and label. The expiry date refers to the last day of that month.

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 to protect the environment.

6. Contents of the pack and other information

What Propylthiouracil Tablets contain

Each tablet contains either 50 mg or 100 mg of propylthiouracil as the active ingredient.

The other excipients in each tablet are starch pregelatinised, lactose monohydrate, sodium starch glycolate (Type-A), povidone K-30 and magnesium stearate.

What Propylthiouracil Tablets look like and contents of the pack

Propylthiouracil 50 mg Tablets are white to off-white coloured, round shaped, biconvex, uncoated tablets debossed with P1 on one side and plain on other side.

Propylthiouracil 100 mg Tablets are white to off-white coloured, round shaped, biconvex, uncoated tablets debossed with P2 on one side and plain on other side.

The tablets are packaged in Alu-Alu blister in packs of 7, 14, 21, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120 or 500 tablets.

Not all pack sizes may be marketed.

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