PACKAGE LEAFLET: Information for the patient

PROPILTIOURACIL

Tablets – 50 mg

(Propylthiouracil)

Read this leaflet carefully before you start taking this medicine.

- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT PROPILTIOURACIL IS AND WHAT IT IS USED FOR

Propylthiouracil inhibits the synthesis of thyroid hormones and thus is effective in the treatment of hyperthyroidism. It does not inactivate existing thyroxine (T4) and triiodothyronine (T3), nor does it interfere with the effectiveness of exogenous thyroid hormones. Propylthiouracil partially inhibits the conversion of (T4) to (T3) in peripheral tissues.

Plasma elimination half-life of propylthiouracil is 1 to 2 hours. The duration of effect is longer than what can be predicted from the plasmatic half-life. The prolonged antithyroid effect makes possible the use of a single daily dose.

Propiltiouracil is indicated in hyperthyroidism.

2. BEFORE YOU TAKE PROPILTIOURACIL

Do not take Propiltiouracil if:

- you are hypersensitive to propylthiouracil or to any of the excipients of Propiltiouracil;
- you are breastfeeding;
- you have severe haematological disorders (mainly granulopenia);
- you suffer from severe hepatic dysfunction;
- you have thyroide toxic adenoma;
- you are under 6 years old.

Warnings and precautions

Ask your doctor or pharmacist before taking Propiltiouracil if:

- the drug will be used in children because it can cause hepatotoxicity. Treatment should be discontinued when the symptoms of liver function disorder appear; some cases of severe hepatic reaction, 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 have symptoms of liver disease, such as: nausea, feeling of being unwell, diarrhea, yellowing of the skin or eyes, dark urine, pale faeces, light bleeding, itching or chills;
- you note that the drug can cause you agranulocytosis;
  Treatment should be discontinued when agranulocytosis, aplastic anemia, hepatitis, fever or exfoliative dermatitis appears;
- you have kidney function impairment.
  In this case the dose should be reduced.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by Propiltiouracil. Please contact your doctor or pharmacist if you are taking or have recently taken other medicines, including those obtained without a prescription. Do not forget to inform your doctor for the treatment with Propiltiouracil if you take any other medicine during treatment, especially the following:

- any mineral supplements in your diet which may contain iodine;

- anticoagulants, propylthiouracil may reduce or strengthen warfarin efficiency, so when combined together, prothrombin time should be constantly checked;
- beta-blocking agents, since propylthiouracil may enhance their effects;
- digitalic glycosides, since propylthiouracil may enhance their levels, which may lead to toxicity;
- theophylline, hyperthyroidism treatment by propylthiouracil may reduce the theophylline clearance.

Taking Propiltiouracil with food and drinks

There are no data if food affects the pharmacokinetics of this drug, but it should be kept in mind that it causes dizziness when this drug is taken with alcohol.

Pregnancy

The potential of Propiltiouracil 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 Propiltiouracil during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby.
Propylthiouracil crosses the placenta. It can be taken during pregnancy, but also can affect the thyroid gland of the unborn baby. If you need to take Propiltiouracil during pregnancy, you should be given the lowest effective dose and your thyroid function should be checked every four to six weeks.

Breastfeeding

Tell your doctor or pharmacist if you breastfeed your baby. Since propylthiouracil passes into breast milk, breastfeeding should not be continued during treatment with this drug.

Driving and using machines

Propiltiouracil may cause dizziness, especially if taken with alcohol. You should not drive or use machinery until you make sure how this drug affects you.

Important information about some of the excipients of Propiltiouracil

Propiltiouracil 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 medicine.

3. HOW TO TAKE PROPILTIOURACIL

Always take Propiltiouracil exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you notice that Propiltiouracil effects are too strong or too weak, talk to your doctor or pharmacist. The tablets should be swallowed with at least half glass of water.

Dosage is as follows:

Adults: *the initial dose*: 300 mg daily, divided into 3 equal doses, every 8 hours.

In patients with severe hyperthyroidism, or very large goiters, the initial dose may be increased to 400 mg daily, sometimes up to 600 - 900 mg daily.

The maintenance dose: 100 - 150 mg daily, in divided doses, every 8 hours.

Children over 10 years*: the initial dose*, 150 - 300 mg daily, in divided doses, every 8 hours.

The maintenance dose: defined as needed.

Children 6 to 10 years: *the initial dose*, 50 to 150 mg daily, in divided doses, every 8 hours. For children, as initial dose can be used 5 - 7 mg / kg body weight per day, in divided doses every 8 hours. *The maintenance dose*: 1/3 - 2/3 of the initial dose, which begins when the patient is euthyroid.

If you take more Propiltiouracil than you should

If you take more Propiltiouracil than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures.

If you forget to take Propiltiouracil

If you forget one dose (or more than one dose), take the next dose in its usual time.

Do not take a double dose (or higher) to make up a forgotten dose(s).
If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Propiltiouracil can cause side effects, although not everybody gets them. Tell your doctor about the following side effects that may occur:
liver failure, liver inflammation, paresthesia, neuritis, headache, dizziness, drowsiness, neuropathy, central nervous system stimulation, depression, exanthema, urticaria, itching, erythema nodosum, skin pigmentation, exfoliative dermatitis, lupus like syndrome (splenomegalia, hepatitis, periartheritis, hypoprothrombinemia, hemorrhagia), loss of taste, sialadenopathy, nausea, vomiting, nephritis, jaundice, hepatitis; myelopoiesis inhibition (eg. agranulocytosis, leucopenia, granulocytopenia, thrombocytopenia), aplastic anemia, hypoprothrombinemia, periartheritis, arthralgia, myalgia, edema, lymphadenopathy, interstitial pneumonia, hypoglycaemia, abnormal hair loss.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROPILTIOURACIL

Keep out of the sight and reach of children!
Do not use Propiltiouracil after the expiry date which is stated on the package.
Do not store above 25°C!
Keep in the original package to protect it from light.

6. FURTHER INFORMATION

What Propiltiouracil contains

The active substance is propylthiouracil.
Each tablet contains 50 mg propylthiouracil.
The excipients are microcrystalline cellulose, maize starch, povidone, lactose monohydrate, sodium lauryl sulphate, purified talc and sodium starch glycolate.

Contents of the pack:

Box with 60 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in September 2023.