

MEDICATION GUIDE

PROPYLTHIOURACIL TABLETS, USP (Proe" pil thye" oh ure' a sil)

Read this Medication Guide before you start taking propylthiouracil and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or treatment.

What is the most important information I should know about propylthiouracil?

- **Severe liver problems. Severe liver problems. In some cases, liver problems can happen in people who take propylthiouracil including: liver failure, the need for liver transplant, or death. Stop taking propylthiouracil and call your doctor right away if you have any of these symptoms**
 - fever
 - loss of appetite
 - nausea
 - vomiting
 - tiredness
 - itchiness
 - pain or tenderness in your right upper stomach area (abdomen)
 - dark (tea colored) urine
 - pale or light colored bowel movements (stools)
 - yellowing of your skin or whites of your eyes
- **Serious risks during pregnancy.** Propylthiouracil may cause liver problems, liver failure and death in pregnant women and may harm your unborn baby. Propylthiouracil may also cause liver problems or death of infants born to women who take Propylthiouracil tablets during certain trimesters of pregnancy. Propylthiouracil may be used when an antithyroid drug is needed during or just before the first trimester of pregnancy.

If you get pregnant while taking propylthiouracil, call your doctor right away about your therapy.

What are propylthiouracil?

Propylthiouracil is a prescription medicine used to treat people who have Graves' disease with hyperthyroidism or toxic multinodular goiter. propylthiouracil is used when:

- certain other antithyroid medicines do not work well.
- thyroid surgery or radioactive iodine therapy is not a treatment option.
- to decrease symptoms of hyperthyroidism in preparation for a thyroidectomy (removal of the thyroid gland) or radioactive iodine therapy.

Propylthiouracil is not recommended for use in children.

Who should not take propylthiouracil?

Do not take propylthiouracil tablets if you are allergic to propylthiouracil or any of its ingredients. See the end of this Medication Guide for a complete list of ingredients in propylthiouracil tablets.

What should I tell my doctor before taking propylthiouracil?

Before you take propylthiouracil, tell your doctor if you:

- plan to have surgery.
- have any other medical conditions
- are pregnant or plan to become pregnant. Talk to your doctor right away if you are pregnant or plan to become pregnant. **Propylthiouracil may harm or cause death of your unborn baby.**
- are breast-feeding or plan to breast-feed. Propylthiouracil can pass into your breast milk. talk to your doctor about the best way to feed your baby if you take propylthiouracil.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Propylthiouracil may affect the way other medicines work.

Especially, tell your doctor if you take:

- a blood thinner medicine warfarin sodium (Coumadin, Jantoven)
- medicine for heart problems
- medicine for high blood pressure
- Digoxin (Lanoxicaps, Lanoxin)
- Theophylline (Elixophyllin, Theolair, Theochron, Theo-24, Uniphyll)

Ask your doctor if you are not sure if your medicine is one of these.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take propylthiouracil?

- Take propylthiouracil exactly as your doctor tells you to take it.
- Your doctor may change your dose if needed.
- Propylthiouracil are usually taken 3 times a day (every 8 hours).
- If you take too much propylthiouracil, call your Poison Control Center or go to the nearest hospital emergency room right away.
 - If you take too much propylthiouracil you may have the following symptoms: nausea, vomiting, upper stomach pain or tenderness, headache, fever, joint pain, and swelling of your body, arms, and legs.
- If you miss a dose of propylthiouracil, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose. Just take the next dose at your regular time. Do not double your dose.

What should I avoid while taking Propylthiouracil?

Propylthiouracil can cause dizziness, drowsiness or sleepiness. If you have these symptoms do not drive, operate machinery, or do other dangerous activities until you know how propylthiouracil tablets affects you.

What are the possible side effects of propylthiouracil?

Propylthiouracil may cause serious side effects, including:

- See “**What is the most important information I should know about propylthiouracil?**”
- **Low white blood cell counts.**
 - This usually happens within the first 3 months of treatment and can be life-threatening. You may have a higher chance of getting an infection when your white blood cell count is low.
 - Call your doctor right away if you have symptoms of infection or illness such as fever, chills, or sore throat.
- **Swelling (inflammation) of the small blood vessels of the body (vasculitis).** Some people have developed vasculitis, a serious complication, during their treatment with Propylthiouracil that can lead to death. Vasculitis can involve the small blood vessels of the skin, kidneys, or lungs. Symptoms may vary depending on which blood vessels are affected.

Tell your healthcare provider right away if you develop changes in your:

- **skin, such as red or purple changes in color, a rash, pain, or swelling,**
- **urine, such as pink or dark in color, looks foamy, decrease in the amount produced, or**
- **breathing, such as shortness of breath or coughing up blood.**
- **Increased risk of bleeding.** You may have increased bleeding especially if you have surgery or if you are taking blood thinners.
- **Hypothyroidism (low thyroid problems).** Your doctor should do blood tests regularly during treatment to check your thyroid.
- **Severe skin reactions (Stevens Johnson syndrome).** Propylthiouracil may cause rare, but serious skin reactions that may require stopping its use. This may need to be treated in a hospital and may be life-threatening. Call your doctor right away or get emergency help if you have skin blisters, peeling rash, sores in the mouth, hives or any other allergic reactions.

The most common side effects of propylthiouracil include:

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| • nausea | • muscle pain |
| • vomiting | • headache |
| • upper stomach pain or tenderness | • sleepiness |
| • joint pain | • nerve pain |
| • itching or tingling | • swelling (edema) |
| • loss or change in taste | • dizziness |
| • loss of hair | • enlarged salivary glands or enlarged lymph nodes |

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of propylthiouracil. For more information, ask our doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1800-FDA-1088.

How should I store propylthiouracil?

Store Propylthiouracil at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86° F).

Keep propylthiouracil and all medicines out of the reach of children.

General information about the safe and effective use of propylthiouracil:

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

Do not use propylthiouracil for a condition for which it was not prescribed.

Do not give propylthiouracil to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about propylthiouracil. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about propylthiouracil that is written for health professionals.

For more information, call 1-888-943-3210 or 1-855-926-3384.

What are the ingredients in propylthiouracil?

Active ingredient: propylthiouracil
Inactive ingredients: microcrystalline cellulose, pregelatinized starch (maize), sodium starch glycolate and magnesium stearate.

Rx only



Manufactured by:
Macleods Pharmaceuticals Ltd.
At Oxalis Labs
Baddi, Himachal Pradesh, INDIA

Manufactured for :
Macleods Pharma USA, Inc.
Princeton, NJ 08540

Medication Guide available at:
www.macleodspharma.com/usa

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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