

PACKAGE LEAFLET: INFORMATION FOR THE USER

PTU

50 mg, tablets

100 mg, tablets

PROPYLTHIOURACIL

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What PTU is and what it is used for
2. Before you take PTU
3. How to take PTU
4. Possible side effects
5. How to store PTU
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1. WHAT PTU IS AND WHAT IT IS USED FOR

PTU is a medicine that contains the active substance propylthiouracil. Propylthiouracil is thioamide derivative, antithyroid medicine used in the treatment of hyperthyroidism in the preparation for the radioactive iodine therapy. It blocks the synthesis of thyroid hormones by interfering with the incorporation of iodine in organic form, ie. inhibits the enzyme peroxidase which is crucial for organification of iodine.

Additionally, it blocks merging of iodinated tyrosine into diiodo tyrosine, while not blocking the taking of iodine in the thyroid gland. As a final effect, there is a decrease of the amount of T3 and T4, both in the gland and in circulation.

Propylthiouracil reversibly inhibits thyroid peroxidase, and the inhibition is dependent on the concentration of free propylthiouracil in the thyroid. Propylthiouracil reduces peripheral de• iodination of thyroxine in the more active triiodothyronine, and it is efficient in thyroid• toxic crisis.

Therapeutic indications

Propylthiouracil belongs to the group of medicines called antithyroids. They reduce the production of the hormone thyroxine from the thyroid gland.

Propylthiouracil tablets are used in the treatment of:

- hyperthyroidism (excessive activity of the thyroid gland);
- preoperative treatment for subtotal thyroidectomy;
- before or after the therapy with radioactive iodine.

2. BEFORE YOU TAKE PTU

Do not take PTU:

- If you are allergic (hypersensitive) to propylthiouracil or any of the other ingredients of the medicine;

In addition, you should not take this medicine if you during its earlier application had some severe side effects, in particular agranulocytosis (damage to bone marrow transplanted with reduced creating of blood cells) or liver damage.

Be careful with PTU if you have:

- Coagulation disorder
- Liver damage
- Difficult ailments of the kidney
- Operation
- Infection

Your doctor will control your recovery at regular visits as long as you are in therapy.

Check with your doctor if any of the following applies to you:

There have been some cases of severe hepatic reactions, in adults and in children, including fatal cases or cases that require a liver transplant. You must immediately inform your doctor if you have symptoms of liver diseases, report such as nausea, vomiting, diarrhoea, yellow skin, dark urine, pale stools, light bleeding, itching, or tremors.

Taking other medicines with PTU

Please inform your doctor or pharmacist about all medicines you are taking or have recently taken, including those that you bought without a prescription.

It is particularly important if you are taking:

- Theophylline, a medicine for the treatment of asthma
- Anticoagulants, medicines that prevent blood clotting
- Beta-blockers, medicine for lowering blood pressure
- Digoxin, a medicine which treat heart rhythm disorders
- Salicylic acid
- phenylbutazone

Taking food and drinks with PTU

The medicine should not be taken together with food.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

Prior to taking the medicine PTU you should tell your doctor if you are pregnant or planning a pregnancy. PTU tablets can be taken during pregnancy, but it can affect the thyroid gland of your unborn child. If you need to

take PTU tablets while you are pregnant, you will get the lowest effective dose, and every four to six weeks, you might want to check the function of your thyroid gland.

You should tell your doctor if you are breast• feeding or you want to start breast feeding while taking PTU tablets. If you need to take PTU tablets while you are breastfeeding, you will get the lowest effective dose, and will need to keep track of your child's development and the function of the thyroid gland.

Driving and using machines

There are no indications that PTU tablets affect ability to drive and use machines.

What you need to know about other ingredients of PTU

PTU medicine contains lactose. If your doctor told you that you have intolerance to some sugars, before you start taking this medicine, you should consult with your doctor.

3. HOW TO TAKE PTU

Always take PTU exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Daily dose of PTU is applied in three individual doses in the range of 8 hours.

Adults

Starting dose is 300-900 mg/day.

After improvements, PTU is used at a dose of 100 to 150 mg/day.

Children

Children under 6 years of age

For children up to six years the dose is determined by a doctor.

Children from 6 to 10 years of age:

For children aged six to ten, the usual starting dose is 50 to 150 mg/day.

Children from 10 years of age and older: the usual starting dose for these children is from 150 to 300 mg/day.

If you have kidney disease or liver disease

If you have kidney or liver disease, your doctor will reduce the dose according to the stage of your diseases.

If you take more PTU than you should

Symptoms of overdose are nausea, vomiting, stomach pain, headache, fever, joint pain, swelling, itching, pallor, frequent infections, weakness, unusual bleeding or unexplained bruising.

If you forget to take PTU

Do not take a double dose to make up for the missed dose.

Take the medicine as soon as you remember if you miss a dose. If it is almost time for your next dose, skip the missed dose, and continue with your regular schedule.

If you stop taking PTU

Therapy is usually gradual discontinued.

If you have any further questions on the use of PTU, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, PTU can cause side effects, which do not occur in all people.

Some patients had nausea, vomiting, discomfort in the stomach, headache, abnormal taste, skin rash, itching or skin rash, joint pain, fever, hair loss.

In rare cases, propylthiouracil can cause problems with the liver. Symptoms include abdominal pain, nausea, loss of appetite, yellow skin and eyes, light colored stool, dark• colored urine. These symptoms could be early signs of liver problems.

Rarely, propylthiouracil can affect the blood and cause a decrease in the number of red and white blood cells and platelets. This can lead to increased risk of infection, severe bleeding, anemia and other problems.

Request medical attention if you notice signs such as fever, pain in the throat, cough, painful and difficult urination (which can point to a small number of white blood cells), unusual bleeding or bruising, small red spots on the skin, bleeding from the nose, black, bloody, or hampered stool, blood in the urine (which can point to a small number of blood platelets) or frequent fatigue and weakness (which can point to the low number of red blood cells).

Some patients have had allergic reactions to propylthiouracil, with cough, swelling of the glands, joint pain, inflammation of blood vessels or pain in the loin area.

Tell your doctor if you experience any, or a combination of symptoms such as joint pain and muscle pain, rashes on the face, difficulty breathing.

In case of any of these symptoms, tell your doctor.

If you notice any side effects, talk to your doctor or pharmacist.

5. HOW TO STORE PTU

Keep out of reach and sight of children.

PTU should not be used after the expiration date stated on the carton. Expiration date refers to the last day of that month.

It does not require any special storage conditions.

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

6. FURTHER INFORMATION

What PTU contains

- Active substance is propylthiouracil.

PTU 50 mg tablets

Each tablet contains 50 mg of propylthiouracil.

- Other substances are: starch, corn; magnesium stearate; lactose monohydrate; cellulose, microcrystalline; silicon dioxide, colloidal anhydrous; starch sodium glycolate; talc powder; gelatin.

- PTU 100 mg tablets

- Each tablet contains 100 mg of propylthiouracil.

- Other substances are: starch, corn; magnesium stearate; lactose monohydrate; cellulose, microcrystalline; silicon dioxide, colloidal anhydrous; starch sodium glycolate; talc powder; gelatin.

What PTU looks like and contents of the pack

PTU tablets are white, round, biconvex tablets with division line on one side.

PTU 50 mg tablets

The tablets are packaged in AL/PVC blister, each with 10 tablets.

The box contains 20 tablets (3 blisters with 10 tablets), along with the attached instructions.

PTU 100 mg tablets

The tablets are packaged in AL/PVC blister, each with 15 tablets.

The box contains 45 tablets (3 blisters with 15 tablets), along with the attached instructions.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer of the medicinal product

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