PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Propyl-Thiocil

Tablets

Composition

Each tablet contains:

Propylthiouracil 50 mg

For information regarding inactive ingredients and allergens, see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat an overactive thyroid gland (hyperthyroidism).

Therapeutic group

A thiouracil-type medicine which belongs to the antithyroid group.

An overactive thyroid gland is a condition in which the thyroid gland produces too much thyroid hormone.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient propylthiouracil or to any of the other ingredients this medicine contains (see section 6 - "Additional information").

Special warnings regarding the use of the medicine

Before treatment with Propyl-Thiocil, inform the doctor if:

- You are pregnant, might be pregnant or are breastfeeding
- You have had any liver or kidney problems in the past
- You are over 40 years old

Contact your doctor immediately before taking this medicine if the following condition applies to you:

You develop symptoms of liver disease, such as nausea, feeling unwell, diarrhea, yellowing of the skin or eyes, dark urine, pale stools, bleeding easily, itching or chills. 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.

Tests and follow-up

During the period of treatment with the preparation, the doctor may refer you for routine blood tests or other tests to check your condition and make sure that you are taking the right dosage.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

Especially if you are taking:

- Mineral dietary supplements containing iodine.
- Medicines that cause a decrease in the number of white blood cells in your body and therefore reduce the body's resistance to infections. If you are unsure, ask your doctor or pharmacist.
- Medicines containing theophylline, aminophylline or digoxin.

Pregnancy, breastfeeding and fertility

Pregnancy

The effect of Propyl-Thiocil on the fetus is unknown.

Inform your doctor immediately if you are pregnant, think you might be pregnant or are planning to become pregnant.

You may be given Propyl-Thiocil treatment during pregnancy if the benefit of the treatment outweighs the potential risk to the fetus.

However, the medicine may affect the thyroid gland of the fetus.

If you need to take the medicine during pregnancy, you should be given the lowest effective dosage and your thyroid function should be checked every four to six weeks.

Breastfeeding

You should inform your doctor if you are breastfeeding or planning to breastfeed while taking the medicine. If you need to take the medicine while you are breastfeeding, you should be given the lowest effective dosage and the baby's development and thyroid function should be monitored.

Fertility

Hyperthyroidism may affect your fertility. Taking Propyl-Thiocil can restore your fertility back to normal.

Important information about some of the ingredients of the medicine

Propyl-Thiocil tablets contain lactose. If you have been told by your doctor that you have an intolerance (sensitivity) to certain sugars, consult your doctor before taking this medicine. The tablet contains 22 mg lactose monohydrate.

This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

Each Propyl-Thiocil tablet contains 0.06 mg of sodium benzoate (E122), which may aggravate jaundice (yellowing of the skin and eyes) in neonates (babies up to 4 weeks of age).

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The dosage and treatment regimen will be determined only by the doctor.

The generally accepted dosage is:

Adults:

Starting dosage: 200-300 mg per day, divided into doses. In patients who suffer from severe hyperthyroidism, very enlarged goiter or both, the starting dosage will usually be 400 mg per day. In some patients, a starting dosage of 600-900 mg per day may be required.

Maintenance dosage: 100-150 mg per day. The dosage can be higher depending on the severity of the patient's condition.

The elderly:

Same dosage as for adults, however, exercise extra caution and even reduce the dosage in case of decreased kidney or liver function.

Children 6-10 years of age:

Starting dosage: 50-150 mg per day.

Maintenance dosage: The dosage will be determined according to the patient's reaction.

Children aged 10 years and above:

Starting dosage: 150-300 mg per day.

Maintenance dosage: The dosage will be determined according to the patient's reaction.

Do not exceed the recommended dose.

Method of use

The medicine should be taken with water.

The tablet may be halved or, if necessary, crushed.

If you accidentally took a higher dosage

It is important not to take too many Propyl-Thiocil tablets. If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. If you remembered when it is almost time for your next dose, skip the forgotten dose and take the next dose only. Do not take a double dose in order to compensate for a forgotten dose.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine

Take the medicine for the period instructed by your doctor. Do not stop taking the medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Propyl-Thiocil may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Contact the doctor immediately if one or more of the following effects occur:

- Fever, sore throat, rashes or ulcers in the mouth and throat, as this could be a sign that you are not producing white blood cells to fight an infection. If this happens the treatment should be stopped. However, this is a rare side effect which occurs most commonly within the first two months of treatment and in patients over the age of 40 who are taking high dosage.
- Fever, joint swelling and pain, muscle pain, blood in the urine, shortness of breath, rash. Propylthiouracil may cause inflammation of the walls of blood vessels which can be serious if not treated. This effect can occur even if you have been taking Propyl-Thiocil for many years.

Tell the doctor if you suffer from any of the following side effects for more than a few days:

- Rash
- Itching
- Hair loss
- Skin discoloration
- Swelling (for example in the legs and feet)
- Nausea and vomiting
- Abdominal discomfort
- Loss of the sense of taste
- Muscle or joint aches
- Prickling and tingling sensation, headache

Additional side effects

Side effects with unknown frequency:

Liver failure, liver inflammation

Rare side effects (side effects that occur in 1-10 out of 10,000 users):

- Anemia, fever, muscle weakness and tenderness, lupus-like syndrome (seen as a red, scaly rash on the nose and cheeks and/or stiffness in the joints and weakness)
- Liver damage or inflammation, which may include jaundice (yellowing of the skin and the whites of the eyes), confusion, coma and death
- Kidney inflammation (blood in the urine), bruising signs and red spots on the skin due to inflammation of the small blood vessels in the skin, shortness of breath and cough
- Slow blood clotting, bleeding and signs of bruising more easily than usual

Your body may produce fewer white blood cells than normal, which may lead to a higher susceptibility to infections. The levels will return to normal when treatment with the medicine is stopped.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dark and dry place, at a temperature below 25°C.**
- Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

Starch, lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, gelatin, magnesium stearate, sodium benzoate (E122)

What does the medicine look like and what are the contents of the package

Propyl-Thiocil tablets are white, flat beveled tablets, one side has a score line and the other side is debossed with "TEVA".

Package sizes: 30 or 90 tablets. Not all package sizes may be marketed.

Name and address of the manufacturer and marketing authorization holder: Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020

This leaflet was revised in April 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health: 026.63.21054

teva