

TIMAZOL TABLET 5MG

Methimazole (5mg)

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What TIMAZOL is used for

TIMAZOL is used to treat hyperthyroidism or overactive thyroid gland (a condition where the thyroid gland produces too much thyroid hormone). It is also used before thyroid surgery or radioactive iodine treatment.

Ask your doctor if you have any questions about why this medicine was prescribed for you. Your doctor may have prescribed it for another reason.

How TIMAZOL works

TIMAZOL contains the active ingredient Methimazole which belongs to a group of medicines called antithyroid agents. It works by reducing the amount of thyroid hormones made in your thyroid gland.

Before you use TIMAZOL

- When you must not use it

Do not take TIMAZOL if:

- You are allergic to methimazole or any ingredients in the formulation or any other similar medicines.
- You are breastfeeding or planning to breastfeed. TIMAZOL may pass into the mother's milk.
- You had inflammation of the pancreas (acute pancreatitis) after administration of carbimazole or methimazole (thiamazole) in the past.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if:

- You have allergies to any other medicines, food, preservatives or dyes.
- You have a low white blood cell count.

- You have joint pain.
- You have liver problems.
- You are taking medications that are known to cause agranulocytosis (decrease in white blood cell count).
- You are allergic to carbimazole or propylthiouracil (other thyroid medications).
- TIMAZOL can cause harm to an unborn baby. If you can get pregnant, use reliable contraception from the time you start treatment and during treatment.
- If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor straight away. Your treatment with TIMAZOL may need to be continued during pregnancy if the potential benefit outweighs the potential risk to you and your unborn baby. However, to reduce the possibility of any effects on your baby, your doctor should prescribe the lowest possible dose and your treatment may be discontinued 3 to 4 weeks before you are due to give birth.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription.

These medicines may be affected by TIMAZOL, or may affect how well it works. In particular tell your doctor or pharmacist if you are taking any of the following:

- Anticoagulants such as warfarin, used to prevent blood from clotting.
- Beta-blockers, used to treat heart conditions and high blood pressure.
- Digitalis glycosides, used to treat heart conditions.
- Theophylline, used to treat asthma or breathing problems.

How to use TIMAZOL

Take your medication exactly as directed by your doctor. You should check with your doctor or pharmacist if you are not sure.

- How much to use

TIMAZOL daily dose usually divided into 3 equal doses, taken orally every 8 hours.

Adult

Initial daily dose:

Mild cases – 15mg daily

Moderate cases – 30mg to 40mg daily

Severe cases – 60mg daily

When the symptoms are controlled the dose should be reduced. The maintenance dose is 1-3 tablets (5 to 15mg) daily.

Children

Initial daily dose: 0.4 mg/kg of body weight

Maintenance daily dose: approximately half of the initial dose.

- When to use it

TIMAZOL may be taken with or without food. Swallow the tablet with a glass of water. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the tablets.

- How long to use it

In order to maintain control of the thyroid gland, you may need to continue to take TIMAZOL for several months. Your doctor will decide when treatment can be stopped. Your doctor may ask you to have occasional blood tests to see how you are responding to treatment.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed. If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the carton or any remaining tablets you have with you.

Symptoms of overdose may include nausea, vomiting, stomach discomfort, headache, fever, joint pain, itchiness and swelling. Symptoms like hepatitis, skin peeling, nerve pain, depression and over excitation could also occur.

Symptoms of decreased white blood cells, red blood cells and platelets may only be

visible after hours or days, which include fever, chills, pallor, easily bruised than normal and gum bleeding.

While you are using it

- Things you must do

- If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking TIMAZOL.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking TIMAZOL.
- Tell your doctor immediately if you become pregnant while taking this medicine.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking TIMAZOL. It may affect other medicines used during surgery.
- Keep all of your doctor's appointments so that your progress can be checked.

- Things you must not do

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or change the dose without checking with your doctor.
- Do not use TIMAZOL to treat any other conditions unless your doctor tells you to.

- Things to be careful of

Be careful while driving or operating machinery until you know how TIMAZOL affects you.

Tell your doctor immediately if you notice any signs or symptoms of infections, in particular sore throat, fever, chills, discomfort.

Check with your doctor immediately if you notice any unusual bleeding or bruising, black tarry stool or blood in urine or stools. Be careful when using toothbrush, dental floss or toothpick.

Observe for loss of appetite, itching, abdominal pain, tiredness or yellow eyes or skin. These are signs of liver problems.

Tell your doctor straight away if you develop:

- fever or abdominal pain, which may be signs of inflammation of the pancreas (acute pancreatitis).

- fatigue, weight loss and muscle and joint pain, which may be signs of inflammation of the blood vessels (vasculitis).

TIMAZOL may need to be discontinued.

Side effects

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

The following side effects may happen with this medicine. Tell your doctor if any of the following symptoms persist or worsen:

- nausea, vomiting
- stomach upset
- skin rash or itching
- change in skin colour
- headache, dizziness
- drowsiness
- hair loss
- heartburn
- loss of taste
- loss of appetite

Tell your doctor right away if you have any serious side effects, including:

- muscle or joint pain
- numbness or tingling feeling
- shortness of breath
- coughing up blood
- swollen lymph nodes
- swollen salivary glands
- signs of liver problems such as persistent nausea/vomiting, yellowing of the skin/eyes, dark urine, severe abdominal pain
- signs of kidney problems such as change in the amount of urine, bloody urine
- inflammation of the pancreas (acute pancreatitis)

TIMAZOL may rarely cause very serious blood disorders (such as a low number of red cells, white cells, and platelets), especially during the first few months of treatment. Tell your doctor right away if you develop any of the following symptoms: signs of infection (such as fever, persistent sore throat), easy bruising or bleeding, unusual tiredness.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of TIMAZOL

Storage

Do not store above 30°C.

Keep medicines in original packaging and away from direct heat, light and excessive moisture.

Do not leave your medicine in the car.

Keep all medicines out of the reach of the children.

- Disposal

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

Product Description

- What it looks like

TIMAZOL is a white round biconvex tablet with a bisect on one side and embossed with "S03" on the other.

- Ingredients

- Active ingredient
Methimazole 5mg

- Inactive ingredients

Lactose monohydrate, microcrystalline cellulose, cornstarch, sodium starch glycolate, croscarmellose sodium, povidone, talcum, colloidal silicon dioxide, magnesium stearate

- Packing

Blister pack of 10 tablets packed in 30, 50, 100, 200 and 500 tablets per box.

- MAL Number

MAL07050041AZ

Manufacturer

Sriprasit Pharma Co., Ltd.
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Product Registration Holder

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