Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Mercaptizol

Tablets

Active ingredient
Each tablet contains:
methimazole 20 mg

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

For treatment of hyperthyroidism.

Therapeutic group: sulfur-containing imidazole derivative.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient methimazole or to any of the other ingredients in this medicine (see section 6).

Special warnings about using this medicine

- **Congenital malformations.** Mercaptizol may cause fetal harm, particularly when taken in the first trimester of pregnancy (see section "Pregnancy and breastfeeding").
- **Agranulocytosis** (lack of neutrophils, a white blood cell type). A life-threatening side effect of Mercaptizol therapy. Immediately report to your doctor any symptoms suggestive of agranulocytosis, including fever, sore throat, headache, rash or malaise. Pay special attention when you are taking other medicines which may cause agranulocytosis (see section 4 "Side effects").
- **Hepatotoxicity.** There have been reports of hepatotoxicity (including acute liver failure) associated with Mercaptizol therapy. The risk of hepatotoxicity appears to be lower with Mercaptizol than with propylthiouracil, another medicine for hyperthyroidism, especially in children. Symptoms suggestive of a liver problem (anorexia, pruritus, right upper quadrant abdominal pain, etc.) require immediate evaluation of liver function and hepatocellular

integrity. In case of a liver function abnormality, your doctor may instruct you to stop treatment with the medicine.
- **Hypothyroidism**. Mercaptizol may cause hypothyroidism, necessitating routine monitoring of thyroid hormone levels (TSH, T4) with adjustments in medicine dosing to maintain normal levels of these hormones.
- If you need any surgery (including dental surgery) or urgent treatment, inform your doctor that you are taking Mercaptizol.
- **Vasculitis (inflammation of blood vessels).** Cases of vasculitis resulting in severe complications have been reported in patients treated with Mercaptizol. **Discontinue therapy and contact your doctor in case of occurrence of vasculitis symptoms**, including rash, blood in urine (hematuria) or decreased urine output, shortness of breath (dyspnea) or hemoptysis (bloody cough) (see section 4 'Side effects').

Children and adolescents
Mercaptizol is the preferred choice when a medicine for hyperthyroidism is required for a pediatric patient.

Tests and follow-up
Since Mercaptizol may cause hypoprothrombinemia (decrease in the level of prothrombin, a procoagulant factor) and bleeding, prothrombin time should be monitored (in blood) during therapy with the medicine, especially before surgical procedures.
Thyroid function tests should be monitored periodically during therapy to determine the maintenance dosage of the medicine.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:
- Oral anticoagulants - Mercaptizol may inhibit vitamin K activity, therefore the activity of oral anticoagulants (e.g. warfarin) may be increased. Your doctor may consider additional monitoring of PT or INR, especially before surgical procedures.
- Beta-adrenergic blockers – A reduced dosage of such medicines may be needed.
- Digitalis glycosides - A reduced dosage of such medicines may be needed.
- Theophylline - A reduced dosage of theophylline may be needed.

Pregnancy and breastfeeding
Pregnancy
If you are pregnant or intend to become pregnant, consult your doctor before using the medicine.
If you become pregnant during treatment with the medicine, inform your doctor immediately.
Mercaptizol use may cause congenital malformations in rare cases; it is therefore preferable to use other medicines in pregnant women with hyperthyroidism, particularly during organogenesis, i.e. in the first trimester of pregnancy. If Mercaptizol therapy is necessary, the lowest possible dosage should be given.

In many pregnant women, thyroid function diminishes along the pregnancy; consequently, a reduction in dosage may be required. In some instances, the therapy will be discontinued by your doctor several weeks or several months before delivery.

Breastfeeding
Consult your doctor if you intend to breastfeed.
Mercaptizol is excreted into breast milk. However, several studies found no effect on clinical status in nursing infants of mothers taking Mercaptizol.
Your doctor should check the thyroid function at weekly or biweekly intervals.

Using this medicine and food
The medicine can be taken with or without food. Ensure regular intake schedule.

Important information about some of this medicine's ingredients
The medicine contains lactose and sucrose. If you have been told by your doctor that you have intolerance to certain sugars, contact your doctor before using this medicine.
The medicine contains Sunset yellow (FD&C Yellow #6 Lake) which may cause allergic reactions.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.
Only your doctor will determine your dosage and how you should take this medicine.

Do not exceed the recommended dose.

- The tablet can be split or crushed.
- Swallow the medicine with some water.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
Symptoms of overdose may include nausea, vomiting, abdominal discomfort, headache, fever, joint pain, pruritus, and edema. Aplastic anemia (lack of blood cells) or agranulocytosis (lack of neutrophils, a white blood cell type) may develop within hours to days. Less common effects include hepatitis, nephrotic syndrome (due to damage to kidneys), exfoliative dermatitis, neuropathy (nervous system disorder), CNS stimulation or depression.

If you forget to take the medicine at the scheduled time, consult your doctor.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. <u>Side effects</u>

Like with all medicines, using Mercaptizol may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Stop using the medicine and contact your doctor immediately in case of:

- Decrease in neutrophils, a white blood cell type (agranulocytosis). Symptoms may include fever, sore throat, rash, headache and malaise.
- Aplastic anemia (decrease in blood cell count), ANCA-positive vasculitis (inflammation of autoimmune etiology), hepatitis, exfoliative dermatitis. Symptoms of liver dysfunction are, for example, anorexia, pruritus, right upper quadrant abdominal pain.

Contact your doctor immediately if you experience any of the following side effects:

- Granulocytopenia (decrease in granulocytes, a white blood cell type), thrombocytopenia (decrease in platelets).
- Fever.
- Lupus-like syndrome.
- Insulin autoimmune syndrome (a syndrome in which the body creates an autoimmune reaction), which can result in diabetic coma due to low blood sugar levels.
- Hepatitis. Symptoms may include jaundice (which may persist for several weeks after discontinuation of the medicine).
- Inflammation of tissues surrounding the arteries (periarteritis).
- Hypoprothrombinemia (abnormally low levels of the coagulation factor prothrombin).
- Nephritis (rare).
- Acute pancreatitis.
- Vasculitis (inflammation of blood vessels), usually associated with appearance of antineutrophilic cytoplasmic antibodies (ANCA), resulting in severe complications (see warnings in section 2).

Additional side effects:

- Skin rash, urticaria, nausea, vomiting, abdominal discomfort, arthralgia, paresthesia, loss of taste, hair loss, myalgia, headache, pruritus, drowsiness, neuritis, edema, vertigo, skin pigmentation, jaundice, salivary gland diseases, lymph node diseases.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home

page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
  Storage conditions
- Store below 25˚C in a cool and dark place.
- Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information:

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

Lactose monohydrate, calcium phosphate dibasic anhydrous, corn starch, confectioner's sugar (97% sucrose, 3% starch), talc, compressible sugar, FD&C Yellow #6 Lake

What the medicine looks like and contents of the pack:
A round, flat, peach-colored tablet, with a score line on one side.
The tablets are packed in a blister. Each pack contains 20 or 30 tablets.
Not all pack sizes may be marketed.

Manufacturer's and Registration holder's name and address: Taro Pharmaceutical Industries Ltd., 14 Hakitor St., Haifa Bay 2624761.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 014-89-24453-00

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