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

The medicine is dispensed with a doctor's prescription only

Prothiazine Syrup 5 mg/5 ml
Each teaspoonful (5 ml) contains:
Promethazine Hydrochloride 5 mg

Prothiazine 25 mg tablets
Each tablet contains:
Promethazine Hydrochloride 25 mg

For inactive ingredients and allergens in the preparation - 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 any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.
Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.
The medicine is not intended for children under the age of 2 years old.

1. What is the medicine intended for?

Prothiazine is an antihistaminic preparation with a tranquilizing effect, for the prevention and relief of allergic reactions, for sedation in states of anxiety and agitation, and it is also used against vomiting and nausea.
Therapeutic class: The active ingredient belongs to the class of antihistamines (phenothiazines).

2. Before using the medicine

Do not use this medicine if:

- The patient is under 2 years of age.
- You are sensitive (allergic) to the active ingredient or to any of the other ingredients this medicine contains (see section 6 – "Additional information"). Signs of an allergic reaction include: rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
- You are taking monoamine oxidase inhibitors (to treat depression) or you have completed treatment with monoamine oxidase inhibitors in the past two weeks.
- The patient is unconscious (or in a coma) or suffering from severe effects of dizziness, drowsiness or headache.

Special warnings regarding the use of the medicine
Before treatment with Prothiazine, inform the doctor if you have:

- Impairment of the respiratory system (breathing difficulties, asthma, bronchitis, wheezing, chest pressure)
- Epilepsy
- Severe heart problems
- Or one of your family members has a history of heart disease
- Irregular heart rhythm
- Liver or kidney problems
- Digestive system or urinary system blockages
- Hearing problems
- Elevated intraocular pressure (glaucoma)
- Reye's Syndrome. Signs include nausea and confusion following a viral disease.
- Prothiazine may make your skin more sensitive to the sun, therefore you should avoid exposure to direct sunlight.

Tests and follow-up
Taking the medicine may affect the results of certain tests, including pregnancy tests and skin assays for allergy. The medicine should be stopped at least three days before beginning skin assays for allergy.
Drug interactions:
Do not use this medicine if you are taking monoamine oxidase inhibitors (to treat depression) or for two weeks after completing treatment with monoamine oxidase inhibitors. See also "Do not use this medicine if".
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:

- Anticholinergic medicines - including medicines for treatment of irritable bowel syndrome, asthma or weak bladder. These medicines may increase the risk of dizziness, dry mouth and blurry vision
- Antipsychotics (such as: Haloperidol and quetiapine)
- Antidepressants (such as amitriptyline and citalopram)
- Tranquilizers and hypnotics (such as diazepam, zolpidem)
- Medicines like aspirin (for the treatment of arthritis and joint pain). Prothiazine may mask the side effects of this medicinal treatment
- Medicines for treatment of irregular heart rate (antiarrhythmics such as: Quinidine and amiodarone)
- Antimicrobial medicines (such as: erythromycin and levofloxacin) for treatment of infections

Use of the medicine and food
The medicine may be taken with or without food.

Use of the medicine and alcohol consumption
Do not drink wine or alcoholic beverages during treatment with this medicine. Alcohol may affect the way this medicine works.
Pregnancy, breastfeeding and fertility
If you are pregnant, may be pregnant or are planning to become pregnant, consult the doctor before using this medicine. Do not take this medicine two weeks before the estimated delivery date.
Do not take this medicine if you are breastfeeding, as small amounts of the medicine may be excreted into breast milk and harm your baby. If you are breastfeeding or are planning to breastfeed, consult the doctor before taking this medicine.
Driving and operating machinery
This preparation may cause sleepiness and drowsiness after taking it or on the morning after. You should be careful when driving and/or when operating machinery that requires alertness.
Children should be cautioned against riding a bicycle or playing near a road etc.
Important information about some of the ingredients of the medicine
Prothiazine Syrup contains:

- 2.67 grams of sucrose in each 5 ml. If you have been told by the doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine. This should be taken into consideration in diabetic patients. May harm your teeth.
- 0.7 grams of sorbitol in each 5 ml. Sorbitol is a source of fructose. If there is a known intolerance to certain sugars, or a diagnosis of hereditary fructose intolerance (HFI), consult your doctor before taking this medicine. Sorbitol may cause digestive system discomfort and may have a laxative effect.
- Glucose. If you have been told by the doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine. May harm your teeth.
- Methyl hydroxybenzoate, Propyl hydroxybenzoate. May cause allergic reactions (possibly delayed).
- Sunset yellow. This may cause allergic reactions.
- **The preparation contains ethanol. Each 5 ml contains about 0.019 ml/15.1 mg ethanol. The ethanol content in the package is 332.2 mg.** The amount of ethanol in 10 ml of this preparation is lower than the amount in 1 ml of beer or wine. This small amount of alcohol in the medicine will not have any noticeable effects.

Prothiazine tablets contains:

- Lactose. If you have been told by the doctor that you have an intolerance to certain sugars, consult your doctor before taking this medicine.
- Ponceau 4R. This may cause allergic reactions.

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 by the doctor only.
The generally accepted dosage is:
For the treatment of allergies:
In children aged 2-5 years: 5-15 ml in one dose to be taken at night or 5 ml two to three times per day.
Do not administer more than 15 ml per day.
In children aged 6-12 years: 10-25 ml in one dose to be taken at night, or 10 ml twice a day. Do not administer more than 25 ml per day.
In children above the age of 12 and adults: Begin treatment by taking one tablet at night. The dosage can be increased up to a maximum of one tablet twice a day, if required.
For the treatment and prevention of nausea and vomiting:
In children aged 2-5 years: 5 ml every 4-6 hours up to a maximum of 15 ml per day.
In children aged 6-12 years: A dose of 10 ml - wait 4-6 hours before administering another dose. Up to two doses per day can be administered. (a total of 20 ml per day).
In children above the age of 12 and adults: One tablet every 4-6 hours up to a maximum of 4 tablets per day.
For short-term use as a sedative and with a doctor's instruction only:
In children aged 2-5 years: 5-15 ml as a single dose to be taken at night, before bedtime.
In children aged 6-12 years: 10-20 ml as a single dose to be taken at night, before bedtime.
Adults: One to three tablets as a single dose, to be taken at night, before bedtime.
If you feel that the effect of the medicine is too weak or too strong, do not change the dose yourself. Consult with the treating doctor.
Do not exceed the recommended dose.
Duration of treatment
Do not take the preparation continuously for more than a week. If the symptoms worsen or if there is no improvement in your condition after seven days, discuss it with the treating doctor.
Method of administration
Tablets: The tablet should be swallowed with a full glass of water.
Crushing/halving/chewing: The tablet should not be halved. If necessary, the tablet may be crushed.
Syrup: Use a measuring cup/spoon, syringe or dropper intended for measuring the correct amount of the medicine. If a cup/spoon or any other measuring device has not been provided with the package, consult a pharmacist. Do not use a household teaspoon to measure the amount of medicine. Household teaspoons vary in size and it is likely you will not receive the correct amount of medicine.
If you have accidentally taken a higher dosage, overdose effects may occur:
In children: agitation, feeling shaky, involuntary movements mainly of the hands or feet, hallucinations, cramps/tremor, loss of consciousness, irregular heart rate and breathing difficulties.
In adults: somnolence, cramps/tremor, loss of consciousness, irregular heart rate and breathing difficulties.
If you took an overdose or if a child swallowed this medicine by mistake, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.
If you have forgotten to take this medicine at the required time, do not take a double dose.
When treating allergy - take the dose as soon as you remember and continue the treatment regimen as before.
When taking the medicine for sedation - skip the dose and take the next evening's dose as usual.
Follow the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects:

As with any medicine, the use of Prothiazine 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.
Discontinue treatment with the medicine and immediately refer to a doctor or proceed to a hospital if one of the following effects occurs:

- An allergic reaction. The signs may include: rash, problems swallowing or breathing, swelling of the lips, face, throat or tongue.
- Liver problems which may cause the eyes or skin to turn yellow/appear yellow (jaundice).
- Muscle tremor or stiffness.
- Abnormal movements of the tongue, facial muscle spasms or lack of control of some facial muscles, eye rolling and tremor.
- Very fast, strong and irregular heartbeats (palpitations).
- General weakness, more frequent infections (especially pharyngitis) and fever as a result of changes in the blood (agranulocytosis).
- Prolonged fatigue. This may be caused by blood problems like anemia.
- Hyperactive behavior in children.

In addition, you should refer to the doctor if the following side effects worsen or continue for more than a few days:

- Dry mouth, blurry vision, disturbance in passing urine.
- Feeling drowsy, somnolence, tiredness, orientation difficulties, nightmares, headaches, agitation.
- Loss of appetite, indigestion or stomach irritation.
- Feeling of dizziness and fainting (reduction of blood pressure).
- Confusion, especially in adults over the age of 65.
- Increased sensitivity upon exposure to the sun. If you experience this effect, avoid direct exposure to the sun and avoid using sun lamps.
- Unpleasant feeling or uncontrollable urge to move the legs (also called restless legs syndrome).

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.) appearing on the package/bottle/carton/label. The expiry date refers to the last day of that month.
- Syrup – store at a temperature below 25°C. Can be used for up to 22 days from opening.
- Tablets – store at a temperature below 25°C.
- Store in the original package.

6. Additional information:

Prothiazine syrup:
In addition to the active ingredient, Prothiazine syrup also contains:
Sucrose, Sorbitol solution, Liquid glucose, Disodium hydrogen Phosphate, Ethanol, Ascorbic acid, Citric acid, Orange flavour 926, Methyl hydroxybenzoate, Propyl hydroxybenzoate, Sunset yellow, Purified water.
Each 5 ml (teaspoonful) of Prothiazine syrup contains 2.7 grams of sucrose and about 3.8 mg of sodium.
Prothiazine tablets:
In addition to the active ingredient, Prothiazine tablets also contains:
Lactose, Maize starch, Methocel E5, Povidone 25, Magnesium stearate, Purified talc, Diethyl Phthalate, Propylene glycol, Polyvinyl acetate phthalate, Colloidal silicone dioxide, Titanium dioxide, Indigo carmine, Ponceau 4R.
Each Prothiazine tablet contains 38.4 mg of lactose.
What does the medicine look like and what are the contents of the package:
Prothiazine syrup is a clear, orange liquid. Each package contains one 110 ml glass bottle.
Prothiazine tablet is purple, round and biconvex. Each pack contains 30 tablets.
Name and address of the Manufacturer and Marketing Authorization Holder: CTS Chemical Industries Ltd.,
3 Hakidma st., Kiryat Malachi.
This leaflet was revised in 03/2024 in accordance with the Ministry of Health guidelines.
Registration numbers of the medicines in the national drug registry of the Ministry of Health:
Prothiazine syrup - 115-73-23131
Prothiazine tablets - 109-46-25265

LFL 207 03/24