

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

The medicine is dispensed with a doctor's prescription only

Prothiazine Expectorant Syrup

Each 5 ml contains:

Promethazine hydrochloride 5 mg

Guaiphenesin 45 mg

Ipecacuanha 10 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.

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 illness is similar.

The medicine is not intended for children under the age of 6 years.

Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.

1. What is the medicine intended for?

The medicine is intended for relieving cough and certain allergic conditions.

Therapeutic class:

Promethazine is an antihistamine
Guaiphenesin and ipecacuanha are expectorants

2. Before using the medicine
Do not use the medicine if:

- The patient is under 6 years of age.
- You are breastfeeding or two weeks before the estimated delivery date.
- You are sensitive (allergic) to the active ingredients 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.
- You are taking this medicine concomitantly with another medicine for relieving cough and cold.
- You are in a state of shock, at a risk of developing seizures, you have blood circulation problems.
- You have liver or kidney problems.

Special warnings regarding the use of the medicine

Before treatment with Prothiazine Expectorant Syrup, inform the doctor if you have:

- Persistent cough or cough accompanied by a lot of phlegm
- 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 rate
- Liver or kidney problems
- Digestive system or urinary system blockages
- Hearing problems
- Elevated intraocular pressure (glaucoma)
- Reye's Syndrome. The signs include nausea and confusion following a viral disease.

- This medicine may make your skin more sensitive to the sun, therefore you should avoid exposure to direct sunlight.

Tests and follow-up

Taking this 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 nutritional supplements, tell the doctor or the pharmacist. In particular, tell the doctor or pharmacist 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

- Antidepressants (such as amitriptyline and citalopram)
- Tranquilizers and hypnotics (such as: diazepam, zolpidem)
- Medicines like aspirin (for 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)
- Antipsychotics (such as: haloperidol and quetiapine)
- Antimicrobial medicines (such as: erythromycin and levofloxacin) for treatment of infections

Use of the medicine and food

Take the medicine after a meal in order to prevent gastrointestinal discomfort.

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 warned to be careful when riding a bicycle or playing near a road etc.

Important information about some of the ingredients of the medicine

Each 5 ml of Prothiazine Expectorant 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.
- 1 gram 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 28.1 mg of ethanol. The ethanol content in the package is 618.2 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.

- Less than 23 mg of sodium per ml, and therefore the medicine is considered sodium-free.

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:

For adults and children above 10 years of age: 10-15 ml two to three times per day.

For children aged 6 to 10 years: 5 ml two to three times per day.

This medicine is not intended for children and babies under 6 years of age.

Do not exceed the recommended dose.

Duration of treatment

Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve after 7 days.

If the cough returns or if the cough is accompanied by fever, rash or a headache that does not go away, stop using the medicine and consult the doctor or pharmacist.

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 you may not receive the correct amount of medicine.

If you accidentally took a higher dosage, overdose effects may occur:

In children: agitation, instability, involuntary movements mainly of the hands or feet, hallucinations, cramps/tremor, loss of consciousness, irregular heart rate and breathing difficulties, vomiting, dehydration, digestive disturbances, heart problems.
In adults: sleepiness, drowsiness, cramps/tremor, loss of consciousness, irregular heart rate and breathing difficulties, vomiting, dehydration, digestive disturbances, kidney stones, heart problems.

If you took an overdose or if a child swallowed this medicine by mistake, refer to the doctor or a hospital emergency room immediately and take the package of the medicine with you.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the scheduled time and consult a doctor.

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 use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Prothiazine Expectorant Syrup 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 (that may be severe and include blisters and peeling of the skin), hives, itch, 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, 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, sleepiness, tiredness, orientation difficulties, nightmares, headaches, agitation.
- Loss of appetite, indigestion or stomach irritation.
- Dizziness and fainting sensation (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).
- Abdominal pain or discomfort.
- Nausea, vomiting, diarrhea, upset stomach.

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. The expiry date refers to the last day of that month.
- Store at a temperature below 25°C.
- Can be used for up to two months from opening.

6. Additional information:

In addition to the active ingredients the medicine also contains:

Sucrose, Sorbitol Solution 70%, Liquid Glucose 80%, Citric Acid, Ethanol 96%, Ascorbic Acid, Orange Oil 926, Monosodium Glutamate, Saccharin Sodium, Methyl Hydroxybenzoate, Disodium Hydrogen Phosphate, Propyl Hydroxybenzoate, Sunset Yellow FCF, Purified Water

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

Prothiazine Expectorant Syrup is a clear, orange liquid. Each package contains one 125 ml glass bottle.

Name and address of the manufacturer/marketing authorization holder: CTS Chemical Industries Ltd., Kiryat Malachi.

This leaflet was revised in 06/2024 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health: 1173023206



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