

PATIENT LEAFLET IN ACCORDANCE

WITH THE PHARMACISTS'

REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Prothiazine Expectorant Syrup

Composition: Each 5 ml contain:

Promethazine Hydrochloride 5 mg

Guaiphenesin 45 mg

Ipecacuanha 10 mg

For a list of inactive ingredients see section 6.

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 physician 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.

The medicine is not intended for children under

the age of 6.

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 temporary relief of

cough due to colds, allergies.

Therapeutic class: Promethazine is an

antihistamine

Guaiphenesin and

Ipecacuanha are expectorants.

2. Before using the medicine:

❑ Do not use this medicine if:

- You are breastfeeding or two weeks before the estimated birth date.
- If there is a known sensitivity to the active ingredient or to any other ingredient the medicine contains. Signs of allergic reaction include: rash, difficulty swallowing or breathing, swelling of the lips, face, throat or tongue.
- The patient is under 6 years old.
- You are taking a medicine for treatment of depression, which belongs to the Monoamineoxidase (MAO's) inhibitors class, or less than two weeks have passed since you stopped taking it (see also "Drug Interactions" section).
- You are taking this medicine together with another medicine for relieving cough and cold medicine.
- The patient is unconscious (in a coma) or if you suffer from a severe dizziness, drowsiness or headache.

❑ Special warnings regarding the use of the medicine:

- This medicine may cause special sensitivity upon exposure to the sun. Therefore, avoid exposure to the sun while using this medicine.
- Children and elderly patients must be under medical supervision due to the fact that they are more sensitive to the side effects.

❑ The medicine should not be used without consulting a doctor before the beginning of treatment if:

- You are suffering from continuing cough or cough accompanied by a significant amount of phlegm.
- You are suffering or have suffered in the past from:
 - Respiratory system dysfunction (Asthma, lung inflammation-bronchitis).
 - Serious heart problem.

- Increased intraocular pressure (narrow-angle glaucoma).
- Liver dysfunction.
- Kidney dysfunction.
- Stomach obstruction.
- Difficulty urinating.
- Diabetes (the preparation contains sugar).
- Epilepsy.
- Reye's syndrome symptoms.

❑ If you are taking or have recently taken other medicines including non-prescription medicines and food supplements, tell the physician or the pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Antidepressants of the Monoamineoxidase inhibitors family – do not use Prothiazine expectorant syrup together with a medicine of the Monoamineoxidase (MAO's) inhibitors family or within two weeks after you have finished taking it.
- Medicines like Aspirin (for treatment of arthritis and joint pains) – Prothiazine may mask the side effects of this medicinal treatment.
- Anticholinergics – including medicines for treatment of irritable bowel syndrome, asthma or weak bladder, may increase the risk for occurrence of dizziness, dry mouth and blurry vision (such as: Atropine and its derivatives).
- Sedatives, hypnotics such as Diazepam or Zolpidem.
- Antidepressants such as Amitriptyline.

❑ Use of the medicine and food:

The medicine should be taken 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 the medicine works.

❑ Pregnancy and breastfeeding

Do not take the medicine two weeks before the estimated birth date or when you are breastfeeding. Prothiazine is secreted into breast milk, which may harm your baby.

If you are pregnant or planning to become pregnant, consult a doctor before using the medicine.

❑ Driving and operating machinery

The preparation may cause drowsiness and sleepiness. You should be careful when driving and/or when operating a machine requires alertness.

Children should be cautioned against riding a bicycle or playing near a road etc.

❑ Important information about some ingredients of the medicine

Each 5 ml of Prothiazine expectorant syrup contain approximately 1.5 mg of Sodium and 3 grams of sugar.

3. How should you use the medicine?

Always use according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be

determined by the doctor only. The generally

accepted dosage is:

For adults and children over 10 years old:

2-3 teaspoons 2-3 times a day.

For children between 6 and 10 years old:

1 teaspoon 2-3 times a day.

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

Be sure to measure the dose with a measuring spoon or a special measuring cup, dropper etc.

Do not exceed the recommended dose

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.

Signs of overdose:

- **In children:** agitation, instability and stumbling, involuntary movements especially of the hands or legs, hallucinations, seizures (convulsions), loss of consciousness, irregular heartbeat and breathing difficulties, vomiting, dehydration, indigestion, heart problems.

- **In adults:** sleepiness, drowsiness, seizures (convulsions), irregular heartbeat, loss of consciousness, breathing difficulties, vomiting, dehydration, indigestion, heart problems.

If you took an overdose or by mistake a child 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, 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 or pharmacist.

Refer to the doctor if signs of the ailment

(symptoms) worsen or do not improve after 7 days.

Do not take medicines in the dark! Check the label

and the dosage every time you take the medicine.

Wear glasses if you need them.

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

4. Side effects:

As with any medicine, use of 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.

Stop using the medicine and contact a doctor or go to a hospital immediately if you experience:

- An allergic reaction. The symptoms may include: rash, blisters, skin peeling, trouble swallowing or breathing, swelling of the lips, face, neck or tongue.
- Liver problems which may cause the eyes or skin to turn yellow (jaundice).
- Muscle tremor or stiffness.
- No control over head or face muscles.
- Abnormal movements of the tongue, face muscles contractions, rolling of the eyes and tremor.

- Very fast, strong or irregular heartbeats (palpitations).
- 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 and throat.
- Blurry vision.
- Difficulty urinating.
- Feeling of sleepiness, drowsiness, fatigue, disorientation\confusion, nightmares, headaches, restlessness.
- Loss of appetite and indigestion.
- Feeling of dizziness and fainting (reduction of blood pressure).
- Confusion, especially in elderly patients.
- Increased sensitivity upon exposure to the sun. If you experience this effect, avoid direct exposure to the sun and avoid using sun lamps.
- Nausea or vomiting.
- Diarrhea.
- Reddening of the skin.
- Unusually thick phlegm.

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

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.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 of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- 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 at a temperature lower than 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.
- **Manufacturer/license holder and address:** CTS Chemical Industries Ltd., 3 Hakidma St., Kiryat Malachi.
- This leaflet was checked and approved by the Ministry of Health in December 2015.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 117-30-23206



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