# PROMEZINE SYRUP 1MG/ML

#### PATIENT INFORMATION LEAFLET

#### What is Promezine Syrup 1mg/ml

Promezine Syrup 1mg/ml is an oral preparation containing 1mg/ml of Promethazine Hydrochloride and inactive ingredients are Sucrose, Alpha Terpineol, Methyl Paraben, Propyl Paraben, Caramel Colour, Cinnamic Aldehyde, Glycerin, Triacetine, Citric Acid, Alpha & Beta Pinene, Sodium Citrate, Maltodextrin, Ascorbic Acid, Disodium Edetate, D-Limonene, Terpinolene, Camphene, Purified Water. Promezine Syrup 1mg/ml appears as brown to dark brown color solution with cola flavor. It is available in plastic bottle of 100ml.

## What is PROMEZINE Syrup 1mg/ml used for

Promezine Syrup 1mg/ml is used to treat the following conditions:

- · As symptomatic relief in allergic conditions e.g. rashes, hives, hay fever
- Symptoms of cold and flu e.g. runny nose
- · Nausea and vomiting
- · Short-term sedation

## How to use Promezine Syrup 1mg/ml

The recommended dose is:

#### As an antihistamine in allergy

| Children 2-5 years  | Either 5-15mg as a single dose or 5mg twice daily.<br>Maximum daily dose 15mg.             |
|---------------------|--|
| Children 6-12 years | Either 10-25mg as a single dose or 5-10mg twice daily.<br>Maximum daily dose 25mg.         |
| Adults              | Initially 10mg twice daily. Increasing to a maximum of 20mg three times daily as required. |

#### · As an antiemetic

| Children 2-5 years  | 5mg every 4 to 6 hours.<br>Maximum daily dose 15mg.               |
|---------------------|---|
| Children 6-12 years | 10mg every 4 to 6 hours as required.<br>Maximum daily dose 25mg.  |
| Adults              | 25mg every 4 to 6 hours as required.<br>Maximum daily dose 100mg. |

#### Short term sedation

| Children 2-5 years  | 5 - 15mg as a single night time dose.   |
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| Children 6-12 years | 10 - 25mg as a single night time dose.  |
| Adults              | 25 or 50mg as a single night time dose. |

#### When not to use Promezine Syrup 1mg/ml

- The person taking the medicine is under 2 years of age.
- The person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache.
- If you are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of Promezine Syrup 1mg/ml.
- If you are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Promezine Syrup 1mg/ml if you have stopped taking one of these MOAI medicines within the last 14 days. If you are not sure ask your doctor or pharmacist.

#### What are the side effects

Like all medicines, Promezine Syrup 1mg/ml can cause side effects, although not everybody gets them.

Stop taking Promezine Syrup 1mg/ml if you notice any of the following side effects:

- An allergic reaction. The signs may include: a rash, itching (pruritus), swallowing or breathing problems, swelling of your lips, face throat or tongue.
- Liver problems that may cause the eyes or skin to go yellow (jaundice).
- · Muscle stiffness or shaking.
- · Being unable to control some muscles in your head and face.
- You notice unusual movements of the tongue, facial muscle spasms, rolling eyes and trembling.
- Very fast, uneven or forceful heartbeat (palpitations).
- Irregular heartbeat.
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
- Over-active behavior in children.

### What are the precaution

Check with your doctor or pharmacist before taking the medicine if

- You have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis).
- You have epilepsy.
- You have any serious heart problems.

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- You have liver or kidney problems.
- You have a stomach blockage or difficulty passing water (urine).
- You have hearing problems.
- You have increased pressure in the eye (narrow angle glaucoma).
  You have had something called Reye's Syndrome or possible Reye's Syndrome signs including being sick and confused following a viral illness.
- Do not drive or use any tools or machine if you feel drowsy or sleepy.

#### Using during pregnancy and nursing mother

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Promezine Syrup 1mg/ml should not be taken 2 weeks before birth.

You should not take Promezine Syrup 1mg/ml if you are breast-feeding. This is because small amounts may pass into mother's milk. This can be harmful to your baby. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

#### What are the symptoms and treatment of overdose

Symptoms of severe over dosage are variable. They are characterized in children by various combination of excitation, ataxia, in-coordination, athetosis and hallucination, while adults may become drowsy and lapse into coma. Convulsions may occur in both adults and children: coma or excitement may precede their occurrence. Tachycardia may develop. Cardiorespiratory depression is uncommon. If the symptom is seen soon enough after ingestion, it should be possible to induce vomiting with ipecacuanha despite the antiemetic effect of promethazine; alternatively, gastric lavage may be used.

Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with diazepam or other suitable anticonvulsant.

### How to keep PROMEZINE Syrup 1mg/ml

Keep in an air tight container. Store at temperature below 30°C. Protect from light and moisture. Keep it out of reach of children. Do not use after the expiry date on the label.

The information contained in this leaflet is limited. Further information can be obtained from your doctor or pharmacist.





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