

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

Promethazine
Hydrochloride Tablets
25mg USP

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Promethazine

Hydrochloride Tablets

25mg USP

Promethazine 25 mg Tablets
promethazine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4. You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

1. What Promethazine Tablets are and what they are used for

2. What you need to know before you take Promethazine Tablets

3. How to take Promethazine Tablets

4. Possible side effects

5. How to store Promethazine Tablets

6. Contents of the pack and other information

1. What Promethazine Tablets are and what they are used for

Promethazine Tablets contain a medicine called promethazine hydrochloride.

This belongs to a group of medicines called

phenothiazines. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction. It also works directly on the brain to help you feel more relaxed.

What Promethazine Tablets are used for
Promethazine Tablets are used to treat the following conditions:

For short term use: to treat adults with difficulty sleeping (insomnia)

To treat allergic conditions such as hay fever or rashes (like nettle rash or hives)

To treat or stop you feeling sick (nausea) or being sick (vomiting) such as travel sickness

For short term use: as a sedative for children aged 5 years and above

2. What you need to know before you take Promethazine Tablets

Do not take this medicine if:

The person taking the medicine is under 5 years of age
You are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of Promethazine Tablets (listed in Section 6 below). The signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

You are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take Promethazine Tablets if you have stopped taking one of these MAOI medicines within the last 14 days. If you are not sure ask your doctor or pharmacist (see "Taking other medicines" section below)

The person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Promethazine Tablets.

Warnings and precautions

Check with your doctor or pharmacist before taking your 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

You have liver or kidney problems

You have a stomach blockage or difficulty passing water

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 include being sick and confused following a viral illness

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Promethazine Tablets.

Other medicines and Promethazine Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Promethazine Tablets can affect the way some medicines work. Also some medicines can affect the way Promethazine Tablets work.

Do not take this medicine, and tell your doctor, if you are taking or have taken the following in the last 2 weeks:

Some medicines for depression called monoamine oxidase inhibitors (MAOIs). If you are not sure ask your doctor or pharmacist

Tell your doctor or pharmacist if you are taking any of the following:

Anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or weak bladder. These can increase the risk of dizziness, dry mouth and blurred eyesight
Medicines for depression (such as amitriptyline)

Medicines to help you to sleep or feel more relaxed (such as diazepam or zolpidem)

Medicines such as aspirin (for arthritis and pain in your joints). Promethazine Tablets may hide the side effects of these medicines

Promethazine Tablets with food and drink

Do not drink alcohol while you are taking

Promethazine Tablets. This is because it can affect the way the medicine works.

Pregnancy and breast-feeding

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant.

Promethazine Tablets should not be taken 2 weeks before birth.

You should not take Promethazine Tablets if you are breast-feeding. This is because small amounts may pass into mothers' 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.

Driving and using machines

You may feel drowsy or sleepy after taking this medicine or the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

Promethazine Tablets contains lactose:

This is a type of sugar. If you have been told by your doctor that you cannot tolerate or digest some sugars (have an intolerance to some sugars), talk to your doctor before taking this medicine

3. How to take Promethazine Tablets

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The amount you need to take depends on the reason you are taking Promethazine Tablets. The following information will help you to decide how much you need to take.

Taking this medicine

Take this medicine by mouth

Do not take for longer than 7 days.

If your symptoms worsen or do not improve after 7 days talk to your doctor or pharmacist

If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

The recommended dose is: For allergies (such as hay fever, rashes and hives)

Children 2-5 years: Promethazine Elixir should be given in this age group

Children 5-10 years: A single tablet (25mg) given at night

DO NOT give more than 25mg each day

Children over 10 years and adults (including the elderly): Start with one tablet (25mg) taken at night

This may be increased to a maximum of one tablet (25mg) twice a day if necessary

For treatment and prevention of feeling sick or being sick (such as travel sickness)

Children 2-5 years: Promethazine Elixir should be given in this age group
Children 5-10 years:

Promethazine Elixir or Promethazine 10mg Tablets should be given in this age group

Children over 10 years and adults (including the elderly): A single tablet (25 mg) to be taken the night before the journey

This may be repeated after 6-8 hours if necessary
As a short term paediatric sedative and for short term treatment of insomnia in adults

Children 2-5 years: Promethazine Elixir should be given in this age group

Children 5-10 years:

A single tablet (25mg) given at night

Children over 10 years and adults (including the elderly): One or two tablets (25mg-50mg) taken at night

Use this medicine only as recommended. Do not exceed the recommended dose.

Exposure to sunlight

Promethazine Tablets can make your skin more sensitive to sunlight. Keep out of direct sunlight while taking this medicine.

If you take more Promethazine Tablets than you should

If you or your child takes more Promethazine Tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you or your child has taken.

The following effects may happen:

In children: Excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet, hallucinations, fits (seizures), loss of consciousness, uneven heart beat and breathing difficulties.

In adults: Feeling sleepy or drowsy, fits, loss of consciousness, uneven heart beat and breathing difficulties.

If you forget to take Promethazine Tablets

Do not take a double dose to make up for a forgotten dose

If you are taking Promethazine Tablets for an allergic condition - take your medicine as soon as you remember, then carry on as before

If you are taking Promethazine Tablets for sedation or sleeping problems - miss that dose and take the next evening's dose as usual

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Tests

Taking Promethazine Tablets may affect the results of certain tests. These include some pregnancy tests and skin tests. Promethazine Tablets should not be taken at least 3 days before the start of a skin test.

4. Possible side effects

Like all medicines, Promethazine Tablets can cause side effects, although not everybody gets them.

Stop taking Promethazine Tablets and see a doctor or go to a hospital straight away if you notice any of the following side effects:

An allergic reaction. The signs may include: a rash, 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 or 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 behaviour in children

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet.

Dry mouth, blurred vision or you cannot pass water (urine)

Feeling drowsy or sleepy, tiredness, disorientation, having nightmares, headaches, feeling restless

Loss of appetite (anorexia), indigestion

Feeling dizzy, lightheaded, faint (hypotension)

Feeling confused, especially in elderly people

Being more sensitive to the sun than usual. If this happens keep out of direct sunlight and do not use sun lamps

Reporting of Side Effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Promethazine Tablets

Keep this medicine out of the sight and reach of children

Do not take Promethazine Tablets after the expiry date which is stated on the carton and blister pack after EXP. The expiry date refers to the last day of that month

Store below 30°C

Store in the original carton in order to protect from light

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other Information

What Promethazine Tablets contains.

Each tablet contains 25mg of the active substance, promethazine hydrochloride
The other ingredients are lactose, maize starch, povidone, magnesium stearate, polyethylene glycol, Opaspray (contains titanium dioxide-E171, hypromellose- E464 and indigo carmine aluminium lake blue-E132) and hypromellose
What Promethazine Tablets look like and contents of the pack

A pale blue film coated tablet marked PN 25 on one side. The tablets are available in blister packs of 56 , 100 and 500 Tablets.

Marketing Authorisation Holder and Manufacturer

Manufactured in India by:
TAJ PHARMACEUTICALS LTD.

Mumbai, India
Unit no 214.Old Bake house,
Maharashtra chambers of commerce lane,
Fort, Mumbai - 400001
at : Ahmedabad-382213, Gujarat, INDIA.
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