

160 x 395 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

PROMETHAZINE HYDROCHLORIDE 25 MG FILM-COATED TABLETS

promethazine hydrochloride

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

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor or pharmacist.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **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.**

WHAT IS IN THIS LEAFLET

1. What Promethazine Tablets is and what it is 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 IS AND WHAT IT IS USED FOR

Promethazine Tablets contains a medicine called promethazine hydrochloride. It belongs to a group of medicines called phenothiazines. It works by blocking the natural substance histamine in your body that causes itching during an allergic reaction. This medicine also has a sedative effect.

can be used in the following situations:

- short-term treatment of sleep disorders
- short-term treatment of anxiety symptoms
- to help you feel more relaxed before an operation or a dental procedure
- to treat or stop motion sickness (e.g. sea sickness)
- to treat allergic reactions of different origins
- to treat or stop you feeling sick and dizzy

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROMETHAZINE TABLETS

Do not take Promethazine Tablets

- if you are allergic to promethazine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are taking a medicine for depression belonging to a group of medicines called monoamine oxidase inhibitors (MAOIs). 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 "Other medicines and Promethazine Tablets" section below).

Promethazine Tablets must not be given to children under 5 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Promethazine Tablets. This is particularly important if you:

- have severe dizziness, drowsiness or headache
- have an enlarged prostate
- have a stomach blockage or have difficulty passing water
- have a severe muscle weakness (myasthenia gravis)
- have liver problems
- are at risk of stroke
- have problems with your heart rhythm
- if you have/have had problems with alcohol, drug or medicine abuse

Due to dryness of the mouth (which is a normal side effect), there is a risk of dental and oral mucosal damage, especially after long-term use. Consequently, you should brush your teeth carefully twice daily with a fluoride toothpaste while taking this medicine.

Treatment with Promethazine Tablets can lead to problems for contact lens wearers as a result of dry eyes.

Taking Promethazine Tablets may affect the results of urine tests for pregnancy which may lead to a false- positive or false-negative result.

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

Other medicines and Promethazine Tablets.

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Do not take this medicine, and tell your doctor or pharmacist, 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

It is also particularly important to tell your doctor or pharmacist if you are taking medicines used for:

- irritable bowel syndrome, asthma or weak bladder (anticholinergic medicines) as these can increase the risk of dizziness, dry mouth and blurred vision
- heart rhythm disturbances and other heart conditions (e.g. flecainide, amiodarone, quinidine and beta- blockers)
- treatment of bacterial infections (e.g. certain antibiotics such as moxifloxacin and erythromycin)
- treatment of fungal infections (e.g. terbinafine)
- pain or drug dependence (e.g. methadone, morphine or morphine-like medicines)
- prevention of malaria (mefloquine)
- intestinal disease (e.g. cisapride)
- mental disorders (e.g. lithium and neuroleptics such as haloperidol, clozapine and risperidone)
- depression (e.g. tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs) such as paroxetine and fluoxetine)
- anxiety (e.g. diazepam)
- sleeping problems (e.g. zolpidem)
- epilepsy

Avoid concomitant treatment with some diuretics (thiazide diuretics), since these can reduce the potassium content in blood and thus increase the risk of heart rhythm disturbances.

Avoid concomitant treatment with anti-anxiety medicines, medicines for sleep problems, strong painkillers (opioids) and other sedative medicines. This can lead to extreme fatigue and unconsciousness, which can be life threatening.

Promethazine Tablets with food, drink and alcohol

Do not drink alcohol while you are taking Promethazine Tablets. This can lead to extreme fatigue and unconsciousness, which can be life threatening.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Reactions may be impaired during treatment with Promethazine Tablets and difficulties adjusting between near and far vision may occur. This should be taken into consideration when alertness is required, for example when driving. These effects may still occur the following morning. Make sure you are not affected before you drive or operate machinery.

Promethazine Tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium- free'.

160 x 395 mm

3. HOW TO TAKE PROMETHAZINE TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not exceed the dose indicated by your doctor. The doctor should prescribe the lowest effective dose for the shortest time possible.

The dose will be determined by your doctor who will customize it for you. For doses which cannot be achieved with Promethazine Tablets other strengths of promethazine hydrochloride medicinal products are available. The lowest effective dose will be used for the shortest time needed. Always take the dose the doctor tells you.

The usual dose is:

Short-term treatment of sleep disorders:

Adults: 25-50 mg 1-2 hours before bedtime. Sometimes the medication is discontinued every third or fourth night.

Short-term treatment of anxiety:

Adults: 25-50 mg, 1-3 times a day.

Before an operation or a dental procedure:

Adults: 25-50 mg one hour before treatment; if necessary, the same dose may be taken the evening before treatment.

Children 6-12 years-of-age: 25 mg one hour before treatment; if necessary, the same dose may be taken the evening before treatment.

Motion sickness:

Adults: 25 mg, 1-2 hours before the trip or alternatively the evening before the trip. If needed, two extra doses can be taken in a 24-hour period.

Allergic conditions:

Adults: 25-50 mg at night.

Nausea and vertigo:

Adults: 25 mg 1-4 times daily

If you take more Promethazine Tablets than you should

If you or your child takes more Promethazine Tablets than you should, contact your doctor at once or go to the nearest hospital casualty department. Take the medicine pack with you. This is so the doctor knows what you have taken. Symptoms of overdose may include fatigue, loss of consciousness, tremors, twitching, headache, hallucinations, seizures, palpitations, redness of skin, high body temperature, large pupils, difficulty urinating, nausea, vomiting. Overdosage can be life threatening, especially if alcohol, drugs and/or certain medicines are taken at the same time (see „Other medicines and Promethazine Tablets“).

If you forget to take Promethazine Tablets

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine 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:

- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Jerky movements and problems such as slowness, muscle stiffness, trembling and feeling restless
- Very fast or uneven heartbeat or chest pains

Other possible side effects:

Common (may affect up to 1 in 10 people)

- Dry mouth.
- Drowsiness. Since Promethazine is usually taken at night, you may feel a little drowsy the following morning. This effect should disappear after a few days of treatment.

Uncommon (may affect up to 1 in 100 people)

- Dry eyes
- Difficulty adjusting between near and far vision
- Constipation
- Difficulty urinating

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. 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 use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions.

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

- The active substance is promethazine hydrochloride. Each tablet contains 25 mg of active substance.
- The other ingredients are:
Tablet core: microcrystalline cellulose (E460), calcium hydrogen phosphate dihydrate (E341), sodium starch glycolate, stearic acid, magnesium stearate (E470B).
Tablet coating: hypromellose (E464), macrogol (E1521), titanium dioxide (E171), talc.

What Promethazine Tablets looks like and contents of the pack

Promethazine hydrochloride 25 mg film-coated tablets are white, oval shaped, 9.8 mm x 6.2 mm biconvex tablets, marked with “C25” on one side and plain on the other side. They are available in blister packs (PVC/PCTFE/PVC foil and lidding aluminium foil).

Pack sizes

20 or 56 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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TVXP170KPA

Customer: Kent

Designer: KBN (AWG)

Product: Promethazine hydrochloride 25 mg film-coated tablets

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Revision:

Launch Of Promethazine
Supersedes: N/A

Colours

