

PROMETHAZINE HYDROCHLORIDE 10 MG TABLETS

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.

What is in this leaflet

1. What Promethazine is and what it is used for
2. What you need to know before you take Promethazine
3. How to take Promethazine
4. Possible side effects
5. How to store Promethazine
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1. WHAT PROMETHAZINE IS AND WHAT IT IS USED FOR

The name of your medicine is Promethazine Hydrochloride 10 mg Tablets, (referred to as Promethazine in this leaflet). It belongs to a group of medicines known as phenothiazines, and works by blocking a substance called histamine that your body makes during an allergic reaction. It also works directly on the brain to help you feel more relaxed.

Promethazine is used to treat the following conditions:

- to treat allergic conditions, such as hay fever or rashes (like nettle rash or hives)
- for short term use: to treat adults with difficulty sleeping (insomnia)
- to treat or prevent you feeling sick (nausea) or being sick (vomiting), such as in travel sickness.
- for short term use: as a sedative for children

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROMETHAZINE

Do not take Promethazine if:

- you are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients in the tablets (listed in section 6). 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) or you have stopped taking one of these MAOI medicines within the last 14 days (See "Taking other medicines" section below).
- the person taking this medicine is under 2 years of age.
- 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 apply to you. If you are not sure, talk to your doctor or pharmacist before taking Promethazine.

Warnings and precautions

Tell your doctor or pharmacist **before** you take this medicine if you:

- have difficulty in breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis)
- have epilepsy
- have any serious heart problems
- have liver or kidney problems
- have a stomach blockage or difficulty passing water (urine)
- have hearing problems
- have increased pressure in the eye (narrow angle glaucoma)
- have suffered from Reye's Syndrome or you have signs of Reye's Syndrome, such as being sick and confused after 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.

You may get high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, hallucinations, or are sweating a lot. This may be signs of a very serious and sometimes deadly health problem called neuroleptic malignant syndrome. Stop taking your medicine and tell your doctor immediately.

There have been some cases of abuse with this medicine. This risk of abuse is greater in those with a history of drug abuse.

Other medicines and Promethazine Tablets

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

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, this includes some medicines used for irritable bowel syndrome, asthma or a weak bladder. These can increase the risk of dizziness, dry mouth, blurred vision.
- other medicines for depression called tricyclic antidepressants, such as amitriptyline or dosulepin
- medicines to help you to sleep or feel more relaxed, such as diazepam or zolpidem
- medicines to relieve pain (for arthritis and pain in your joints), such as aspirin. Promethazine may hide the side effects of these medicines.

Tests

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

Promethazine tablets with food and drink

Do not drink alcohol while you are taking Promethazine. Alcohol may increase the sedative effects of Promethazine and make you feel very drowsy.

Pregnancy and breast-feeding

Talk to your doctor before taking Promethazine if you are pregnant or planning to become pregnant. Promethazine should not be taken 2 weeks before birth.

You should not take Promethazine if you are breastfeeding. This is because small amounts may pass into the mothers' milk. This could 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 day after you have taken this medicine. If this happens, do not drive or operate any machines.

Promethazine Tablet contains lactose and sucrose

This medicine contains **lactose** and **sucrose** (types of sugars). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking Promethazine.

3. HOW TO TAKE PROMETHAZINE

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. The following information will help you to decide how much you need to take.

Taking this medicine

- Swallow the tablets whole with a glass of water
- 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, ask your doctor.

How much to take

The usual doses are:

For allergies (such as hay fever, rashes and hives)

Children 2-5 years: A liquid form of this medicine should be used in this age group.

Children 5-10 years: A single dose of either one or two tablets (10 mg or 20 mg) given at night or one tablet (10 mg) given twice a day. DO NOT give more than two tablets (20 mg) each day.

Children over 10 years and adults (including the elderly): Start with one tablet (10 mg) twice a day. This may be increased to a maximum of two tablets (20 mg) three times a day.

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

Children 2-5 years: A liquid form of this medicine should be used in this age group.

Children 5-10 years: A single tablet to be taken the night before the journey. This may be repeated after 6-8 hours if necessary.

Children over 10 years and adults (including the elderly): Two tablets (20 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: A liquid form of this medicine should be used in this age group.

Children 5-10 years: Two tablets (20 mg) given as a single dose at night time.

Children over 10 years and adults (including the elderly): Two to five tablets (20 mg to 50 mg) as a single dose at night time.

Children under 2 years

DO NOT give this medicine to children under 2 years of age.

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 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 occur:

- **In children:** excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet, hearing or seeing things that are not there (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

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

- If you are taking Promethazine for an allergic condition - take your medicine as soon as you remember, then carry on as before.
- If you are taking Promethazine 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

STOP TAKING this medicine 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 of which may include a rash, swelling of the face, lips, tongue or throat, difficulty in breathing or swallowing, sudden wheezing or collapse
- liver problems which may cause yellowing of the skin or whites of the eyes (jaundice)
- muscle stiffness or shaking
- being unable to control some muscles in the head or face
- unusual movements of the tongue, facial muscle spasms, rolling eyes and trembling
- very fast, uneven or forceful heart beat (palpitations)
- irregular heartbeat

- changes in the numbers and types of your blood cells. If you notice increased bruising, nosebleeds, sore throats, infections, excessive tiredness, breathlessness or abnormal paleness of the skin, you should tell your doctor who may want you to have a blood test.
- over-active behaviour in children

Not Known: frequency cannot be estimated from the available data

- You have high fever, muscle cramps or stiffness, dizziness, very bad headache, fast heartbeat, confusion, agitation, hallucinations, or are sweating a lot. This may be signs of a very serious and sometimes deadly health problem called neuroleptic malignant syndrome

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

- dry mouth, blurred vision, constipation, difficulty shedding tears or passing urine, especially in the elderly and children
- feeling drowsy or sleepy, tired, disorientated or restless
- feeling confused, especially in the elderly
- feeling depressed, having nightmares or problems sleeping, headaches
- loss of appetite (anorexia), indigestion, stomach upsets
- feeling dizzy, lightheaded or faint (hypotension)
- skin rash, itching, red and raised lumps (hives)
- being more sensitive to the sun than usual. If this happens keep out of direct sunlight and do not use sun beds.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PROMETHAZINE

Keep out of the sight and reach of children.

Store below 25°C. Store in the original packaging and keep the blister packs in the outer carton.

Do not use the tablets after the expiry date, which is stated on the carton and blister packs. The expiry date refers to the last day of that month.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Promethazine Hydrochloride 10 mg Tablets contain

The active substance is promethazine hydrochloride. Each tablet contains 10 mg of the active substance.

The other ingredients in the tablets are lactose, maize starch, pregelatinised maize starch, magnesium stearate, bleached shellac, talc, titanium dioxide (E171), povidone, sucrose, beeswax, carnauba wax and Opalux blue which also contains patent blue (E131), indigo carmine (E132) and sodium benzoate (E211).

What Promethazine Hydrochloride 10 mg Tablets look like and contents of the pack

Promethazine Hydrochloride 10 mg Tablets are blue, sugar-coated tablets, which are available in blister packs of 16 and 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chelonia Healthcare Limited,
11 Boumpoulinas, Nicosia, P.C. 1060, Cyprus

Manufacturer

DDSA Pharmaceuticals Limited,
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For more information about this product, please contact the Marketing Authorisation Holder.

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