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PACKAGE LEAFLET: INFORMATION FOR THE USER

**PROMETHAZINE HYDROCHLORIDE
25 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 after 7 days.

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
6. Contents of the pack and other information

1. WHAT PROMETHAZINE IS AND WHAT IT IS USED FOR

The name of your medicine is Promethazine hydrochloride 25 mg tablets (called Promethazine in the leaflet). Promethazine 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.

Promethazine is used to treat the following conditions:

- 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: to treat adults with difficulty sleeping (insomnia).
- for short term use: as a sedative for children aged 5 years and above.

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 of this medicine (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.
- the person taking this medicine is under 6 years of age.
- you are taking a medicine for depression called a monoamine oxidase inhibitor (MAOI). Also do not take promethazine if you have stopped taking one of these MAOI medicines within the last 14 days (See "Other medicines and Promethazine" section below). If you are not sure, ask your doctor or pharmacist.
- 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.

Warnings and precautions

Talk to your doctor or pharmacist **before** taking Promethazine if you:

- experience an allergic reaction (see section Side Effects), seek medical help right away.
- develop a fever or an infection. Talk to your doctor immediately as laboratory tests to check your blood count may be required.
- have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis).
- have epilepsy.
- have any serious heart problems.
- have any personal or family history of heart disease.
- have an irregular heartbeat
- have liver or kidney problems.
- have a stomach blockage or difficulty in passing water.
- have hearing problems.
- have increased pressure in the eye (narrow angle glaucoma).
- have had something called Reye's Syndrome or possible Reye's Syndrome signs include being sick and confused after a viral illness.

- phenothiazine derivatives may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal (sudden death). QT prolongation is exacerbated, in particular, in the presence of bradycardia, hypokalaemia, and acquired (i.e. drug induced) QT prolongation.

Children and adolescents

Do not use in children less than 6 years of age. Because of the risk of choking, the tablets should be avoided in children who have difficulty swallowing tablets.

Exposure to sunlight

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

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.

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

Other medicines and Promethazine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines bought without a prescription, including herbal medicines. This is because Promethazine can affect the way some medicines work. Also some medicines can affect the way Promethazine works.

Special caution is required when promethazine is used concurrently with drugs known to cause QT prolongation (such as antiarrhythmics, antimicrobials, antidepressants, antipsychotics) to avoid exacerbation of risk of QT prolongation.

In particular, 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.

Also tell your doctor or pharmacist if you are taking, have recently taken or might take any of the following:

- anticholinergic medicines, this 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 mental health problems (antipsychotics such as haloperidol and quetiapine) or depression (antidepressants such as amitriptyline and citalopram).
- medicines to help you sleep or feel more relaxed (such as diazepam or zolpidem).
- medicines such as aspirin (for arthritis and pain in your joints). Promethazine may hide the side effects of these medicines.
- medicines for the treatment of irregular heartbeats (antiarrhythmics such as quinidine and amiodarone).
- antimicrobials (such as erythromycin and levofloxacin) for the treatment of infections.
- medicines for the treatment of epilepsy or seizures.

Promethazine with alcohol

Do not drink alcohol whilst taking Promethazine. This is because it can affect the way the medicine works.

Pregnancy and breast-feeding

Use of Promethazine is not recommended during pregnancy.

Talk to your doctor or pharmacist before taking this medicine if you are pregnant, might become pregnant, or think you may be pregnant. Promethazine should not be taken 2 weeks before birth.

You should not take Promethazine if you are breast-feeding. This is because small amounts may pass into the mother's 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, dizzy or sleepy or have blurred vision after taking this medicine or the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

You should not drive a vehicle or operate machinery until you know how Promethazine affect you.

Promethazine contains lactose monohydrate and sucrose

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

3. HOW TO TAKE PROMETHAZINE

Always take 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

- Take this medicine by mouth.
- **Do not take it for longer than 7 days.** If your symptoms worsen or do not improve after 7 days talk to your doctor or pharmacist.
- Use this medicine only as recommended. Do not exceed the recommended dose.
- 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 doses are:

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

Adults (including the elderly) and children over 10 years:

- Start with 1 tablet (25 mg) taken at night.
- This may be increased to a maximum of 1 tablet (25 mg) twice a day if necessary.

Children 6-10 years:

- A single tablet (25 mg) given at night.
- DO NOT give more than 25 mg per day.

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

Adults (including the elderly) and children over 10 years:

- A single tablet (25 mg) taken the night before the journey.
- This may be repeated after 6 to 8 hours if necessary.

Children 6-10 years:

- A liquid form of this medicine should be given.

As a short-term sedative for children and for short term treatment of insomnia in adults

Adults (including the elderly) and children over 10 years:

- 1 or 2 tablets (25 mg to 50 mg) taken at night.

Children 6-10 years:

- A single tablet (25 mg) given at night.

If you take more Promethazine than you should

If you or your child accidentally takes more Promethazine 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.

High doses (supratherapeutic doses) can cause ventricular arrhythmias including QT prolongation and torsade de pointes.

The following symptoms of an overdose may occur:

- fits (seizures), loss of consciousness, coma, uneven heartbeat and breathing difficulties. Children may experience excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet, hallucinations, limited ability to learn and impairments in thinking, learning, or memory.

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, this medicine can cause side effects, although not everybody gets them.

Frequency "not known (cannot be estimated from the available data)":

- abnormal electrical activity of the heart that affects its rhythm, including life-threatening rhythm disturbance
- a serious reaction with fever, rigid muscles, changing blood pressure and coma (neuroleptic malignant syndrome)
- low levels of blood platelets (which can lead to bleeding and bruising)
- restlessness
- hallucinations
- aggression

STOP TAKING this medicine and see a doctor or go to a hospital straight away if you notice any of the following side effects:

- **allergic reactions** (that can occur either immediately or within several days of drug administration) that may be life-threatening. Symptoms may include rash, itching, difficulty breathing, shortness of breath, swelling of the

face, lips, throat, or tongue, cold, clammy skin, palpitations, dizziness, weakness or fainting

- liver problems which may cause eyes or skin to go yellow (jaundice) and darkening of urine
- muscle stiffness or shaking
- unusual movements of the tongue, facial muscle spasms, being unable to control some muscles in your face, rolling eyes and trembling
- over-active behaviour in children
- very fast, irregular, uneven or forceful heartbeat (palpitations)
- general weakness, more frequent infections (particularly throat infection) and fever due to changes in the blood (agranulocytosis)
- tiredness which lasts for a long time. This may be due to a blood problem called anaemia
- QT prolongation, torsade de pointes
- eosinophilia which is an increase in the number of eosinophils (a type of white blood cell). Eosinophilia will be detected by a blood test
- thrombocytopenia which is a decrease in the number of platelets (cells in the blood that help with clotting) found in a blood test, which can lead to bleeding and bruising (thrombocytopenic purpura)
- a feeling of aggression, hallucinations and hyperactivity in children.

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 or you cannot pass water (urine).
- feeling drowsy or sleepy, tiredness, disorientation, having nightmares, headaches, feeling restless.
- feeling confused, especially in elderly people.
- loss of appetite (anorexia), indigestion or irritated stomach.
- feeling dizzy, lightheaded or faint (hypotension).
- being more sensitive to the sun than usual. If this happens keep out of direct sunlight and do not use sunlamps.
- unpleasant sensation or an overwhelming urge to move the legs (also called Restless Legs Syndrome).

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

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 package or container after EXP. The expiry date refers to the last day of that month.

Store below 25°C and protect from light. Store in the original package or container and keep the container tightly closed.

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 contains

The active substance is promethazine hydrochloride. Each tablet contains 25 mg of promethazine hydrochloride.

The other ingredients are lactose monohydrate, maize starch, starch pregelatinised, magnesium stearate (E572), purified talc (E553b), shellac (E904), titanium dioxide, povidone, PB-605010 (indigo carmine aluminum lake (E132) and titanium dioxide (E 171)), sucrose, beeswax yellow (E901) and carnauba wax (E903).

What Promethazine looks like and contents of the pack

Promethazine tablets are blue, sugar-coated tablets which come in blister packs of 10, 14, 28, 30 and 56 tablets and in containers of 100, 500 and 1,000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Chelonia Healthcare Limited,
Boumpoulinas 11, 3rd Floor, 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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