PATIENT INFORMATION LEAFLET - INFORMATION FOR THE USER

PROMETHAZINE TEOCLATE 25mg TABLETS

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take Promethazine Teoclate Tablets carefully to get the best results from them.
- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. **What Promethazine Teoclate Tablets is and what it is used for**
2. **Before you take Promethazine Teoclate Tablets**
3. **How to take Promethazine Teoclate Tablets**
4. **Possible side effects**
5. **How to store Promethazine Teoclate Tablets**
6. **Further information**

1. What Promethazine Teoclate Tablets is and what it is used for

Promethazine Teoclate 25mg Tablets (hereinafter referred to as Promethazine Teoclate Tablets) are an anti-emetic (anti-sickness drug) which helps to prevent, and treat nausea and vomiting, including travel sickness, and vertigo.
Promethazine Teoclate Tablets contains promethazine which belongs to a group of medicines called phenothiazines. Your doctor may prescribe this medicine for giddiness or light- headedness (vertigo), or for sickness after an operation, and in such cases the tablets should be taken as instructed by your doctor.

2. Before you take Promethazine Teoclate Tablets

Do not give to a child under 2 years old.
Do not take Promethazine Teoclate Tablets if you have:
- ever had an allergic reaction to promethazine, any phenothiazine or any of the ingredients (see section 6 for more details). The signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- taken medicines for depression, known as Monoamine Oxidase Inhibitors (MAOIs) within the last 14 days. If you are not sure ask your doctor or pharmacist (see 'Other medicines and Promethazine Teoclate Tablets')
- CNS depression. People with CNS depression will seem sleepy or unconscious (including coma).

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 Teoclate Tablets.

Warnings and precautions for use
Check with your doctor or nurse before having Promethazine Teoclate Tablets if:
- You have glaucoma (increased pressure in the eye)
- You have epilepsy
- You have any serious heart problems
- You have any personal or family history of heart disease
- You have an irregular heartbeat
- You have liver problems
- You have kidney or bladder problems
- You have a chest condition such as asthma or bronchitis
- You have severe headaches with blurred vision, severe stomach pains with vomiting, dizziness, difficulty with keeping your balance, ringing in the ears or other ear problems as well as feeling sick
- You have a bad cough
- You have Reye's Syndrome or symptoms of Reye's Syndrome (including persistent vomiting, feeling tired or sleepiness).
- You experience an allergic reaction (see section 4), seek medical help right away.
- You develop a fever or an infection. Talk to your doctor immediately as laboratory tests to check your blood count may be required.
- You have a stomach blockage or difficulty passing water.
- You have hearing problems.

Do not take Promethazine Teoclate Tablets for more than 7 days without contacting your doctor.

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

Tests
Taking Promethazine Teoclate Tablets may affect the results of certain tests. These include some pregnancy tests and skin tests. Promethazine Teoclate Tablets should not be taken at least 72 hours 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 Teoclate Tablets.

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

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

Taking Promethazine Teoclate Tablets with food and drink
While taking Promethazine Teoclate Tablets, you should avoid drinking alcohol as the tablets will add to the effects of alcohol.

Pregnancy and breast-feeding
Use of Promethazine Teoclate Tablets is not recommended during pregnancy. Talk to your doctor or pharmacist before taking this medicine if you are a woman of childbearing age and not using effective contraception, or if you are pregnant, might become pregnant, or think you may be pregnant. Promethazine Teoclate Tablets should not be taken 2 weeks before birth.
You should not take Promethazine Teoclate Tablets if you are breastfeeding. This is because small amounts may pass into mothers' milk. This can be harmful to your baby.
If you are breastfeeding or planning to breastfeed, talk to your doctor or pharmacist before taking any medicine.

(continued overleaf)

Driving and operating machinery
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 Teoclate Tablets affect you.
Important information about some of the ingredients in this product
These tablets contain sodium metabisulphite which may rarely cause hypersensitivity (allergic) reactions and bronchospasm (difficulty breathing). These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. How to take Promethazine Teoclate Tablets

Always take Promethazine Teoclate Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:

Adults
For the prevention of travel sickness on long journeys
Take one tablet each night at bedtime starting the night before you travel.
For the prevention of travel sickness on short journeys
Take one tablet one or two hours before travelling.
Treatment of travel sickness
Take one tablet as soon as you feel sick followed by a second tablet the same evening. Take a third tablet the next evening if necessary.
Nausea and vomiting due to other causes
One tablet each night is usually enough, but two or three tablets may be required by some patients. These can be taken at intervals during the day, but it is often not necessary for more than 4 tablets to be needed in any 24 hour period.
Children over 10 years old
Give the lower adult dose (one tablet).
Children 5 - 10 years old
Give half the lower adult dose (half a tablet).
Children 2 - 5 years old
Promethazine Teoclate Tablets are not suitable for children 2 - 5 years old. An oral liquid is recommended.
Do not give to a child under 2 years old.
Do not take Promethazine Teoclate Tablets for more than seven days. Should symptoms persist for or do not improve after 7 days, talk to your doctor or pharmacist.
Avoid strong sunlight while taking this product as your skin may be more sensitive to the effect of the sun.
If you take more Promethazine Teoclate Tablets than you should:
Talk to your doctor, pharmacist or go to the nearest hospital casualty department immediately.
If you forget to take Promethazine Teoclate Tablets
If you forget to take a tablet, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Stop taking Promethazine Teoclate Tablets 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 that may cause the eyes or skin to go yellow (jaundice) and darkening of urine
- Muscle stiffness or shaking
- Unusual movements of the tongue, facial muscle spasms or being unable to control some muscles in your face, rolling eyes and trembling
- 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)
- 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).
- Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.
- A feeling of aggression, hallucinations and hyperactivity in children

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:
- 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 or irritated stomach
- 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
- 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, pharmacist or nurse. 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 Teoclate Tablets

Keep this product out of the sight and reach of children. Do not use after the expiry date printed on your pack. Store in the original container.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Promethazine Teoclate Tablets contains
Each tablet contains the active ingredient promethazine teoclate 25mg.
Promethazine Teoclate Tablets also contains: lactose, sodium metabisulphite (E223), potato starch, dextrin, microcrystalline cellulose, stearic acid and magnesium stearate.
What Promethazine Teoclate Tablets looks like and contents of the pack
Promethazine Teoclate Tablets are white to pale cream, plain, circular biconvex tablets marked 'PT' on one side with a score line on the reverse. They are available in cartons of 10 or 28 tablets and plastic containers of 60 tablets. Not all pack sizes may be marketed.
Marketing Authorisation Holder:
Manx Pharma Ltd, Unit 2, Bosworth Avenue, Tournament Fields, Warwick, CV34 6UQ, UK
Manufacturer:
Manx Healthcare Ltd, Unit 2, Bosworth Avenue, Tournament Fields, Warwick, CV34 6UQ, UK
Other formats
To request a copy of this leaflet in Braille, large print or audio please call 01926 482511.

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