

**Approved Patient Information Leaflet for PROMETHAZINE HCl 25 mg FRESENIUS and
PROMETHAZINE HCl 50 mg FRESENIUS**

SCHEDULING STATUS

S5

PROMETHAZINE HCl 25 mg FRESENIUS

PROMETHAZINE HCl 50 mg FRESENIUS

Solution for injection

Each 1 ml solution contains 25 mg promethazine hydrochloride.

Contains antioxidants:

ascorbic acid 0,2 % *m/v*

sodium metabisulphite 0,1 % *m/v*

sodium sulphite 0,1 % *m/v*.

Sugar free.

Read all of this leaflet carefully before you are given PROMETHAZINE HCl FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What PROMETHAZINE HCl FRESENIUS is and what it is used for
2. What you need to know before you are given PROMETHAZINE HCl FRESENIUS
3. How you will be given PROMETHAZINE HCl FRESENIUS
4. Possible side effects
5. How to store PROMETHAZINE HCl FRESENIUS

6. Contents of the pack and other information.

1. What PROMETHAZINE HCl FRESENIUS is and what it is used for

What PROMETHAZINE HCl FRESENIUS is

The active ingredient, promethazine hydrochloride, is a so-called phenothiazine, an organic compound that occurs in various antipsychotic and antihistaminic medicines. It works by preventing the effects of a substance called histamine, which is produced by the body. Histamine can cause itching, sneezing, runny nose, and watery eyes.

What PROMETHAZINE HCl FRESENIUS is used for

- To relieve or prevent the symptoms of hay fever, irritation and redness in the membrane covering the eye (known as allergic conjunctivitis), allergic skin reactions (such as itching, hives) and other types of allergy.
- To treat serious, potentially life-threatening allergic reactions (known as anaphylactic or anaphylactoid reactions) in conjunction with adrenaline.
- To prevent and treat motion sickness, with signs like nausea, vomiting and dizziness.
- To make you less anxious before and after a surgical operation and to help treat nausea and vomiting afterwards.
- To treat a symptom of Parkinson's disease characterised by uncontrolled rolling of the eyeballs (known as oculogyric crises).

2. What you need to know before you are given PROMETHAZINE HCl FRESENIUS

You should not be given PROMETHAZINE HCl FRESENIUS:

- If you are hypersensitive (allergic) to promethazine hydrochloride or any of the other ingredients of PROMETHAZINE HCl FRESENIUS (listed in section 6).
- You have any allergies to sodium sulphites.
- If the person is younger than two years of age, the injection should not be administered, as it has been linked to sudden infant death syndrome (SIDS).

- You are experiencing an asthma attack, or you are in a coma (a state of unconsciousness).
- You are already too calm and drowsy due to other medicines or alcohol.
- You have been told by a doctor that your bone marrow does not function adequately (your blood has been tested and your doctor diagnosed you with blood disorders).
- You have a liver disease, or a doctor told you that your liver does not work satisfactorily.
- You have been told by a doctor that you have pheochromocytoma (a tumour of the adrenal glands).
- You have been diagnosed with Reye's syndrome (it is a very serious disorder associated with viral infection and aspirin use).
- You are taking medicines known as monoamine oxidase inhibitors (MAOIs), as these medicines will strengthen the sedative effect of PROMETHAZINE HCl FRESENIUS. Ask your doctor or pharmacist if the medicines you are taking for depression or high blood pressure are MAOIs.

Warnings and precautions

Tell your doctor or healthcare provider before being given PROMETHAZINE HCl FRESENIUS if:

- You have a heart or coronary artery (narrowing of arteries) disease.
- You have an enlarged prostate.
- You suffer from increased pressure inside the eyeballs, known as narrow angle glaucoma.
- You have a destructive lung condition with loss of elasticity (known as emphysema) or chronic inflammation of the air passages of the lungs (known as bronchitis).
- You have a hereditary disease of body metabolism known as porphyria.
- You suffer from recurrent fits (epilepsy).
- You have yellowing of the skin or whites of the eyes (jaundice) caused by liver or blood problems.
- You have a nervous disorder characterised by tremor, stiffness and shuffling (known as parkinsonism).
- You have diabetes mellitus, a disease that causes high blood sugar.

- Your pituitary glands produce insufficient amounts of thyroid hormones (known as hypothyroidism).
- You have a muscle disorder causing weakness (known as myasthenia gravis).
- You are currently suffering from an asthma attack.
- Your liver or kidneys does not function normally due to a liver or kidney disease.
- You have an obstruction of the bladder neck or not being able to urinate.
- You have an internal obstruction that prevents gastric outflow.
- Your child is younger than two years old.
- Your child is dehydrated (lost a lot of water, perhaps due to vomiting or diarrhoea).
- You are older than 65 years, as you may more easily get side effects.

You should also know that:

- Skin tests for allergy should be postponed as PROMETHAZINE HCl FRESENIUS may suppress the reaction on the test allergens.
- PROMETHAZINE HCl FRESENIUS may cause false negative or false positive results on pregnancy tests.
- PROMETHAZINE HCl FRESENIUS may cause that blood sugar tests do not yield accurate results.

Other medicines and PROMETHAZINE HCl FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

This is especially important with the following medicines as they may interact with PROMETHAZINE HCl FRESENIUS:

- Sedatives or tranquillisers (also known as CNS depressants), used to treat insomnia, anxiety, panic attacks and seizures.
- Medicines for high blood pressure known as MAO inhibitors.
- Antidepressants such as amitriptyline or maprotiline.

- Medicine used in the treatment of Parkinson's disease such as levodopa.
- Antibiotics used to treat infections such as aminoglycosides.
- Medicines used for high blood pressure.
- Medicines used for epilepsy.

Receiving PROMETHAZINE HCl FRESENIUS with food, drink and alcohol

You should not take alcohol together with PROMETHAZINE HCl FRESENIUS as it will suppress your mental alertness and make you too sleepy and sedated.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before receiving PROMETHAZINE HCl FRESENIUS.

PROMETHAZINE HCl FRESENIUS should not be used during pregnancy, especially in the 2 weeks prior to delivery, as it may cause irritability and excitement in your new-born baby.

PROMETHAZINE HCl FRESENIUS should not be used while breastfeeding as it may cause jaundice (affecting the liver with yellow skin and eyes) and nervous damage (extreme restlessness, involuntary movements) in your baby.

Driving and using machines

PROMETHAZINE HCl FRESENIUS may make you feel drowsy and affect your concentration. Do not drive a vehicle or operate machines as PROMETHAZINE HCl FRESENIUS could interfere with your ability to do so safely.

PROMETHAZINE HCl FRESENIUS contains sodium sulphite

PROMETHAZINE HCl FRESENIUS contains sodium sulphite, which may cause allergic reactions and a tight chest.

3. How you will be given PROMETHAZINE HCl FRESENIUS

PROMETHAZINE HCl FRESENIUS is normally administered in hospital, by a doctor or professional healthcare provider.

Your doctor will tell you how long your treatment with PROMETHAZINE HCl FRESENIUS will last. Your doctor will decide what dose you should receive, and whether you should get a repeat injection. This will vary from patient to patient. It will depend on your symptoms, desired effect and other factors, such as your physical condition, body mass, age as well as other medicines that you are taking at the time.

If you receive more PROMETHAZINE HCl FRESENIUS than you should

Since a healthcare provider will administer PROMETHAZINE HCl FRESENIUS, he/she will control the dosage. However, in the event of overdose your doctor will manage the overdose.

Some of the signs of overdose are extreme drowsiness or excitement (particularly in children), hallucinations (seeing or hearing things that do not really happen), dry mouth and a flushed face. Please tell your doctor or healthcare professional if you have any concerns; he/she will take appropriate supportive measures, if necessary.

If you missed a dose of PROMETHAZINE HCl FRESENIUS

Since a healthcare provider will administer PROMETHAZINE HCl FRESENIUS, it is unlikely that a dose will be missed.

4. Possible side effects

PROMETHAZINE HCl FRESENIUS can have side effects.

Not all side effects reported for PROMETHAZINE HCl FRESENIUS are included in this leaflet.

Should your general health worsen or you experience any untoward effects while receiving PROMETHAZINE HCl FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, stop administration of PROMETHAZINE HCl FRESENIUS immediately:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PROMETHAZINE HCl FRESENIUS. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following after receiving PROMETHAZINE HCl FRESENIUS:

- Tight chest.
- Changes in the way your heart beats, for example if your heart beats very fast, irregular, slower than usual or if you can feel your heart beating (palpitations).
- Signs of recurrent infections such as fever or sore throat, as you may have a severe decrease in white blood cells which makes infections more likely (known as agranulocytosis or leukopenia).
- Less urine than is normal for you with pain and difficulty while urinating.
- Yellowing of the skin and eyes, dark urine and tiredness, which may be symptoms of liver problems.
- Increased bleeding or bruising due to a reduction in blood platelets (known as thrombocytopenia).

- Reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness (known as haemolytic anaemia).

These are serious side effects. You may need urgent medical attention.

Tell your doctor if you experience any of the following reactions after receiving PROMETHAZINE HCl FRESENIUS:

Frequent side effects:

- Drowsiness, lack of energy, tiredness, dizziness and incoordination.
- Increased blood pressure or occasional low blood pressure.

Less frequent side effects:

- Being more sensitive to the sun than usual.

Side effects with unknown frequency:

- Confusion, hallucinations (seeing and hearing things that do not exist), convulsions (uncontrollable contraction of muscles).
- Blurred or double vision.
- Ringing in the ears, tingling in the arms or legs.
- Headache.
- Difficulty in falling asleep, nightmares.
- Unrealistic feeling of well-being.
- Irritability and shaking.
- Dry mouth, thickening of mucous and coughing.
- Loss of appetite, nausea and vomiting, diarrhoea or constipation and pain on the stomach.
- Temporary fever while receiving the injection, known as drug fever.
- Increased sweating.
- Pain, burning, redness and warm skin at the site of the injection. This may lead to serious complications such as tissue death if not treated immediately. Your doctor will stop giving you PROMETHAZINE HCl FRESENIUS and you will be given urgent medical attention.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

Healthcare providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of PROMETHAZINE HCl FRESENIUS.

5. How to store PROMETHAZINE HCl FRESENIUS

- Store at or below 25 °C. Protect from light.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the bag.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PROMETHAZINE HCl FRESENIUS contains

Each 1 ml of sterile solution contains:

promethazine hydrochloride 25 mg.

The other ingredients are ascorbic acid, hydrochloric acid (for pH-adjustment), sodium chloride, sodium hydroxide (for pH-adjustment), sodium metabisulphite, sodium sulphite (anhydrous) and water for injection.

What PROMETHAZINE HCl FRESENIUS looks like and contents of the pack

PROMETHAZINE HCl FRESENIUS solution for injection is a clear, colourless to slightly straw-coloured solution.

PROMETHAZINE HCl 25 mg FRESENIUS:

1 ml amber Type 1 glass ampoules.

PROMETHAZINE HCl 50 mg FRESENIUS:

2 ml amber Type 1 glass ampoules.

10 ampoules are packed into a blister tray. Each blister tray is packed into a cardboard carton.

Holder of Certificates of Registration and Manufacturer

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