For The Use of A Registered Medical Practitioner or A Hospital or A Laboratory

Rx

Promethazine Hydrochloride Injection I.P.

Composition :

Each ml contains :

Promethazine Hydrochloride IP 25 mg

Water for Injection IP q.s.

AMERICAN
Promargan
Injection
For I.M./I.V. Use Only

1.What Promethazine Injection is and what it is used for: Promethazine Injection contains 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.**What Promethazine Injection is used** for To treat allergic conditions such as hay fever or rashes (like nettle rash or hives) As a sedative for both adults and children. This is a medicine given to reduce awareness or make you feel relaxed and at ease .To treat adults with difficulty sleeping (insomnia).To help you feel more relaxed before an operation.

2 What you need to know before you are given Promethazine Injection: Do not use this medicine if: The person taking the medicine is under 2 years of age You are allergic (hypersensitive) to promethazine hydrochloride or any of the other ingredients of Promethazine Injection 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). Also do not take Promethazine Injection 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 The person is unconscious (in a coma) or suffers from severe dizziness, drowsiness or headache You should not be given this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before having Promethazine Injection.**Warnings and precautions** Do not have this medicine and tell your doctor if:You have difficulty breathing, wheezing, tightness in the chest (asthma) or an infection in your lungs (bronchitis),You have epilepsy,You have any serious heart problems,You have liver or kidney problems,You have a stomach blockage or difficulty passing water,You have a headache due to dehydration or high blood pressure,You have increased pressure in the eye (narrow angle glaucoma),You have had something called Reye's Syndrome or possible Reye's Syndrome – signs include being sick and confused following a viral illness,If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before having Promethazine Injection.Other medicines and Promethazine Injection Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you can buy without prescription, including herbal medicines. This is because Promethazine Injection can affect the way some medicines work. Also some medicines can affect the way Promethazine Injection 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 - 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 depression (such as amitriptyline) Medicines to help you to sleep or feel more relaxed (such as diazepam or zolpidem) Medicines such as aspirin (for arthritis and pain in your joints). Promethazine Injection may hide the side effects of these medicines Medicines for high blood pressure Medicines for fits (epilepsy) Medicines for diabetes. Your doctor may need to change the dose of your medicine.Promethazine Injection with food and drink Do not drink alcohol while you are having Promethazine Injection. This is because it can affect the way the medicine works.Pregnancy and breast-feeding Talk to your doctor before having this medicine if you are pregnant, might become pregnant, or think you may be pregnant. You should not have Promethazine Injection 2 weeks before you give birth.You should not have Promethazine Injection if you are breast-feeding. This is because small amounts may pass into mothers' milk. This can be harmful to your baby. If you are breast-feeding or planning to breastfeed, talk to your doctor or pharmacist before taking any medicine.**Driving and using machines** You may feel drowsy, dizzy or confused while having this medicine or in the morning after taking this medicine. If this happens, do not drive or use any tools or machines.

3.How Promethazine Injection will be given: Your medicine will normally be given to you by a doctor or nurse. This is because it needs to be given by a deep injection into a muscle or by a slow injection into the vein.Having this medicineThis medicine is usually given by a deep injection into a muscle. It can also be given by a slow injection into the vein after dilution using water for injection.If you feel the effect of your medicine is too weak or too strong, tell your doctor.If you are not sure why you are being given Promethazine Injection or have any questions about how much Promethazine Injection is being given to you, speak to your doctor or nurse.Exposure to sunlight Promethazine Injection can make your skin more sensitive to sunlight.Keep out of direct sunlight while taking this medicine.If you have more Promethazine Injection than you should It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will be monitoring your progress, and checking the medicine that you are given. Always ask if you are not sure why you are getting a dose of medicine.The following effects may happen:In children: Excitation, moving unsteadily or stumbling, uncontrolled writhing movements especially of the hands or feet, 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 miss a dose of Promethazine Injection Your doctor or nurse will have instructions on when to give you this medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However if you do think you have missed a dose, tell your doctor or nurse.If you have any further questions on the use of this product, ask your doctor or nurse.Tests Having Promethazine Injection may affect the results of certain tests. These include some pregnancy tests and skin tests. Promethazine Injection should not be given at least 3 days before the start of a skin test.

4.Possible side effects: Like all medicines, Promethazine Injection can cause side effects, although not everybody gets them.Tell a doctor or nurse straight away if you have:An allergic reaction. The signs may include: a rash, hives, itchiness swallowing or breathing problems, swelling of your lips, face, throat or tongue Liver problems that may cause the eyes or skin to go yellow (jaundice) Muscle stiffness or shaking.Being unable to control some muscles in your head or face.You notice unusual movements of the tongue, facial muscle spasms, rolling eyes and trembling.Very fast, uneven or forceful heartbeat (palpitations).Tiredness which lasts for a long time. This may be due to a blood problem called anaemia.Over-active behaviour in children.Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days. Also tell them if you notice any side effects not listed in this leaflet.Dry mouth, blurred eyesight or you can not pass water (urine).Feeling drowsy or sleepy, tiredness, disorientation, having nightmares, headaches, feeling restless.If you have a headache this may be as a result of high blood pressure and/or dehydration and you are advised to see your doctor.Loss of appetite (anorexia), sore 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.

5.How to store Promethazine Injection: This medicine will be kept by your doctor or pharmacist in a safe place where children cannot see or reach it.Do not have Promethazine Injection after the expiry date which is stated on the carton and ampoule after EXP. The expiry date refers to the last day of that month.Store in the original carton in order to protect from light.Do not throw away any medicines via wastewater or household waste.Ask your pharmacist how to discard medicines you no longer use.These measures will help protect the environment

6.Contents of the pack and other Information: What Promethazine Injection contains Each 2ml ampoule contains 50mg/2ml of the active substance, promethazine hydrochloride The other ingredients are phenol and water for injection.What Promethazine Injection looks like and contents of the pack Promethazine Injection is a clear, colourless or almost colourless solution. Your solution for injection is available in cartons containing 2ml ampoules.

Storage: Store protected from light.

Improper storage may deteriorate the active ingredients.

Keep the medicine out of reach of children.

Dosage : As directed by the Physician.

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Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex,
Bhiwandi, Mumbai - 421302 ●E-mail: info@americanremedies.in
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