

Package leaflet: Information for the user
Prochlorperazine Mesilate 12.5mg/ml Solution for Injection
prochlorperazine

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Prochlorperazine Injection is and what it is used for
2. What you need to know before you are given Prochlorperazine Injection
3. How you will be given Prochlorperazine Injection
4. Possible side effects
5. How to store Prochlorperazine Injection
6. Contents of the pack and other information

1. What Prochlorperazine Injection is and what it is used for

Prochlorperazine Injection belongs to a class of drugs called phenothiazine neuroleptics. It influences the activity of certain brain cells by decreasing the effect of dopamine, a natural chemical in the brain.

Prochlorperazine Injection may be used to improve the symptoms of major mental disorders such as in schizophrenia, acute mania, and short term treatment of anxiety. It may also be used

to treat the symptoms of nausea (feeling sick) and vomiting (being sick), as well as symptoms of vertigo due to Menieres syndrome or labyrinthitis (inner ear disorders).

2. What you need to know before you are given Prochlorperazine Injection

You should not be given Prochlorperazine Injection:

- If you are allergic to prochlorperazine or any of the other ingredients of this medicine (listed in section 6).
- If the person is a child. This is because children may develop unusual face and body movements (dystonic reactions).

Warnings and precautions

Talk to your doctor or pharmacist or nurse before you are given Prochlorperazine Injection if you:

- suffer from any disease involving the heart and blood vessels (cardiovascular disease) including chest pain (angina) and irregular heart beats
- have a problem with your liver or kidneys
- have high blood pressure due to a tumour of a gland situated on top of the kidney (a condition known as pheochromocytoma)
- suffer from a brain disorder causing tremors, rigidity and slowing of movement (Parkinson's disease)
- suffer from fits (epilepsy)
- suffer from an eye disease called narrow angle glaucoma which causes increased pressure inside the eye

- have or have ever had a low number of white blood cells (agranulocytosis). This would lead you to get infections more easily than usual
- have ever had a stroke
- have dementia
- have low blood levels of potassium, calcium and magnesium. Your doctor may perform blood tests to check on these
- are not eating properly or are very underweight
- have a history of alcohol problems
- have depression
- are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely
- have abnormal muscle weakness (Myasthenia gravis)
- suffer from an enlargement of prostate gland (which will result in difficulty in passing water)
- are exposed to extremes in temperature as this medicine can affect body temperature control
- have an underactive thyroid gland
- are an elderly person
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

Children and adolescents

Intramuscular prochlorperazine should not be used in children under 18 years.

Other medicines and Prochlorperazine Injection:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The effects of these medicines may change, especially if you are taking:

- sleeping tablets or sedatives (e.g. phenobarbital) that can make you sleepy
- medicines which result in lowering of blood pressure or treat migraine (e.g. guanethidine or clonidine)
- anticholinergic medicines for stomach problems or used to reduce saliva and lung secretions (e.g. atropine, procyclidine)
- antidepressants (e.g. other phenothiazines, lithium)
- medicines for fits (anticonvulsants)
- medicines for Parkinson's disease (e.g. levodopa)
- medicines for asthma or to relieve a stuffy nose or used in eye drops (adrenaline or sympathomimetic drugs)
- medicines used to treat diabetes
- medicines used to treat iron poisoning (desferrioxamine)
- antacids used to treat indigestion
- medicines used to control heart beat such as propranolol
- medicines used for the treatment of cancer (cytotoxics)
- medicines used for infection (antibiotics)
- amfetamines used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Prochlorperazine Injection with food, drink and alcohol

You should not drink alcohol whilst you are being given this medicine.

Pregnancy and breast-feeding

You should not be given Prochlorperazine Injection if you are pregnant, think you may be pregnant or are planning to become pregnant, or while breast feeding, unless your doctor decides that treatment is essential. It is particularly important not to take Prochlorperazine Injection during the first three months of pregnancy.

The following symptoms may occur in newborn babies, of mothers that have used prochlorperazine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

Prochlorperazine Injection may make you feel drowsy or dizzy or give you blurred vision. You should not drive or use machines when you are first given this medicine until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

Prochlorperazine Injection contains sodium sulphite and sodium metabisulphite:

This medicine contains less than 1mmol sodium (23mg) per ml, that is to say essentially 'sodium-free'. This medicine also contains the preservatives sodium sulphite (E221) and sodium metabisulphite (E223) which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How you will be given Prochlorperazine Injection

Your doctor will decide on a dose and duration of Prochlorperazine Injection therapy which is right for you.

Prochlorperazine Injection is only given in the hospital by a doctor.

Prochlorperazine Injection is usually given by injection deep into the muscle. Your doctor will decide on a suitable dose depending on your age, severity of the symptoms and previous responses to similar medicines.

For mood disorders and schizophrenia, it may take several weeks for you to feel the full benefit of this medicine.

Elderly

A smaller starting dose should be given to elderly patients.

Use in children and adolescents

Prochlorperazine Injection is not for use in children.

If you are given more Prochlorperazine Injection than you should

As Prochlorperazine Injection is administered by a healthcare professional it is unlikely that you will be given too much. If you are at all concerned, speak to your doctor.

In this event, you will be treated in the hospital and you will be given the necessary treatment.

If you miss a dose of Prochlorperazine Injection

This is unlikely as the injection is given by a healthcare professional but if you are concerned about missing a dose, speak to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

You should avoid:

- Exposure to direct sunlight (or sunbeds) if you are receiving a high dose of this medicine as it could cause your skin to over react to sunlight. Your doctor may advise you to use a sunblock

- Getting the injection solution on your skin as it could cause a type of skin rash (dermatitis).

If you notice any of these symptoms seek medical advice immediately:

- Some patients may experience a local lump at the site of injection, difficulty in sleeping, stuffy nose or dry mouth, agitation.
- Allergic reactions, where signs may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- There have been reports of jaundice (yellowing of skin and whites of eyes) eye problems, skin colouring (pigmentation) and blood problems.
- Patients may develop Neuroleptic Malignant Syndrome. This causes a high temperature, rigid muscles, drowsiness, occasional loss of consciousness, and requires emergency admission to hospital for treatment.
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing.

Tell your doctor straight away if you notice any of the following:

- Patients may experience a fast or irregular heartbeat, constipation, difficulty or inability to pass urine or a high temperature
- Prochlorperazine Injection can lead to breast enlargement in men or to inappropriate milk production or altered menstrual cycle (e.g. periods stop) or erectile dysfunction
- Some patients have complained of feeling slowed down, whilst others of being agitated
- Feeling weak or light-headed, especially just after standing up (this commonly occurs just after the injection has been administered)
- A problem with your breathing
- Medicines such as Prochlorperazine Injection can have effects on muscle control. If this happens, symptoms can include slurred speech, odd movements of the face, particularly of the tongue, eyes, head or neck (such as twisting of the neck which causes an unnatural positioning of the head, rigid muscles, tremors or restlessness and difficulty in sitting still).
- Some patients (especially on high doses of this medicine) experience problems with muscle control which may continue for years. Such patients may experience constant chewing or tongue movements or other gentle movements of the neck, head or trunk. Uncontrollable movements of the arms and legs have also been reported in these patients
- In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics
- If you have angina and your pain is getting worse
- If you suffer from a sore throat, high fever, feel very tired, become pale, develop bruises and nose bleeds. Fever may occur 1-3 weeks after treatment. These may indicate blood problems developing as a result of using this medicine
- Tremor, rigidity, slowed ability to start and continue movements, and impaired ability to adjust the body's position
- High blood sugar (symptoms can include excessive thirst, passing large amounts of urine, weight loss and feeling very tired)

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Website: 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 Prochlorperazine Injection

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 ampoule and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

If only part of the solution is used, the remainder should be discarded.

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 Prochlorperazine Injection contains

- The active substance is prochlorperazine mesilate.
- The other ingredients are anhydrous sodium sulphite (E221), sodium metabisulphite (E223) and ethanolamine in water for injections.

What Prochlorperazine Injection looks like and contents of the pack

Prochlorperazine Injection is a colourless or almost colourless sterile solution. Each 1ml of solution contains 12.5mg of prochlorperazine mesilate. The solution is presented in 1ml and 2ml clear glass ampoules.

Each carton contains either 5 or 10 ampoules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mercury Pharmaceuticals Ltd,
Dashwood House, 69 Old Broad Street,
London, EC2M 1QS, United Kingdom.

Manufacturer

B. Braun Melsungen AG, Mistelweg 2, 12357 Berlin, Germany.

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