

PACKAGE LEAFLET: INFORMATION FOR THE USER
Stemetil® 12.5 mg/ml Solution for Injection -1 ml Ampoule
Prochlorperazine Mesilate

Is this leaflet hard to see or read? Phone 01 4035600 for help

Read all of this leaflet carefully before you start having 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 or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

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

Stemetil Injection contains a medicine called prochlorperazine mesilate. This belongs to a group of medicines called 'phenothiazine antipsychotics'. It works by blocking the effects of a chemical in the brain.

Stemetil Injection can be used to:

- Treat balance problems or dizziness (vertigo). This includes problems of the inner ear such as 'Meniere's Syndrome'
- Stop you feeling sick (nausea) or being sick (vomiting). This can be from any cause including migraines
- Treat schizophrenia
- Treat over-active behaviour or thoughts (mania)
- Treat anxiety in the short-term, when used in addition to other medicines

2. What you need to know before you take Stemetil Injection

Do not have this medicine and tell your doctor if:

- You are allergic (hypersensitive) to prochlorperazine mesilate, other phenothiazine medicines such as chlorpromazine or any of the other ingredients of Stemetil Injection (listed in Section 6 below) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have liver problems
- The patient is a child. This is because children may develop unusual face and body movements (dystonic reactions)

Warnings and precautions

If you experience an allergic reaction (see section “Possible side effects”) contact your doctor or other healthcare professional immediately or go to the nearest hospital emergency room right away.

Talk to your doctor or pharmacist before having Stemetil Injection if:

- You have heart problems or a family history of heart problems
- You have ever had a stroke or your doctor has considered you are at increased risk of a stroke
- You have unusual fast beating of your heart or low blood pressure
- You have liver or kidney problems
- You have thyroid problems
- You have an enlarged prostate gland. This means you may have problems when passing water (urine)
- You have Parkinson’s disease
- You have dementia
- You have epilepsy or have ever had fits (seizures)
- You have depression
- You have a tumour on your adrenal gland called ‘phaeochromocytoma’
- You have a type of muscle weakness called ‘myasthenia gravis’
- You have or have ever had glaucoma (signs include painful eyes with blurred vision)
- You have or have ever had a low number of white blood cells (agranulocytosis). This would lead you to get infections more easily than usual
- You have low blood levels of potassium, calcium and magnesium. Your doctor may perform blood tests to check on these
- You are not eating properly or are very under-weight
- You have a history of alcohol problems
- You have diabetes or are at increased risk of developing diabetes
- You or someone in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- You are elderly (65 years of age or older)

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

Talk to your doctor or pharmacist when you are having Stemetil Injection if (see section 4):

- You have increased sensitivity of your skin to sunlight. You should avoid exposure to direct sunlight while taking this medicine.
- You have problems with any movements and/or walking
- You have an unusually pale complexion, sweating, high or low temperature, fast heartbeat, stiff muscles, fast breathing and feel confused, drowsy or agitated.

Tests

Your doctor may do regular tests while you are taking this medicine. These might include blood tests, eye checkups and an ECG to check your heart is working properly. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Other medicines and Stemetil Injection

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

In particular, tell your doctor if you are taking any of the following:

- Medicines to help you sleep (sedatives, barbiturates)
- Other medicines used to calm emotional and mental conditions
- Medicines used for depression
- Medicines used for Parkinson's disease such as levodopa
- Medicines for fits (epilepsy) such as carbamazepine
- Medicines used to control your heartbeat such as diltiazem and verapamil, digitalis, amiodarone, disopyramide, propranolol or quinidine
- Medicines for high blood pressure such as doxazosin, terazosin, guanethidine or clonidine
- Medicines used for diabetes
- Medicines used for cancer (cytotoxics)
- Medicines used for infections (antibiotics)
- Medicines for indigestion and heartburn (antacids)
- Medicines which may induce a drop in potassium level in the blood (hypokalemia) such as hypokalaemic diuretics, stimulant laxatives, IV amphotericin B, glucocorticoids.
- Anticholinergic medicines - includes some medicines used for irritable bowel syndrome, asthma or incontinence
- Amphetamines - used for Attention Deficit Hyperactivity Disorder (ADHD)
- Adrenaline - used for life threatening allergic reactions
- Desferroxamine - used when you have too much iron in your blood
- Lithium - used for some types of mental illness

Stemetil Injection with alcohol

Do not drink alcohol while you are having Stemetil Injection. This is because alcohol can add to the effects of Stemetil Injection and can cause serious breathing difficulties.

Pregnancy and breast-feeding

Stemetil should be avoided during pregnancy and breastfeeding. Talk to your doctor or pharmacist before taking this medicine if you are pregnant, think you may be pregnant or intend to become pregnant. You should not be given this medicine when breast-feeding, as small amounts of Stemetil can pass into breast milk and affect your baby (see section 4).

Driving and using machines

Stemetil Injection may cause drowsiness, blurred vision or dizziness. If this happens do not drive or operate any tools or machines. Tell your doctor or pharmacist.

Stemetil Injection contains:

- **Sodium:** This medicine contains less than 1 mmol of sodium (23 mg) per 1 ml ampoule, that is to say essentially 'sodium-free'.
- **Sulphites:** This medicine contains small amounts of sulphites. These may cause severe allergic (hypersensitivity) reactions and difficulty in breathing (bronchospasm). This is more likely to happen if you have a history of asthma or allergies. The chances of this happening are rare. Stop having the medicine if you get a rash, swallowing or breathing problems or swelling of your lips, face, throat or tongue

3. How Stemetil Injection is given

Stemetil Injection is normally given by a doctor or nurse. This is because it needs to be given as a deep injection into a muscle.

How much Stemetil Injection is given

If you are not sure why you are being given Stemetil Injection or have any questions about how much Stemetil Injection is being given to you, speak to your doctor or nurse. The usual doses are:

Schizophrenia and other psychotic disorders:

Adults: 25 - 75 mg per day in divided doses

You will be given injections until you are able to take Stemetil Tablets

Treatment of migraine or stopping you feeling sick or being sick:

Adults: To begin with 12.5 mg by injection

This may be followed by oral medication 6 hours later if necessary

Elderly: Your doctor may prescribe a lower dose. You should be careful during very hot or very cold weather to make sure that you do not get too hot or too cold.

Children: Stemetil Injection is not given to children

If you have more Stemetil Injection than you should

It is unlikely that your doctor or nurse will give you too much medicine. Your doctor and nurse will monitor your progress and check the medicine you are given. Always ask if you are not sure why you are getting a dose of medicine. Having too much Stemetil may make you feel sleepy or dizzy, increased or rapid heartbeat, feeling very cold and confused, writhing movements, feeling restless, stiffness or shaking. You may lose consciousness.

If you miss a dose of Stemetil 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 stop having Stemetil Injection

Keep having Stemetil Injection until your doctor tells you to stop. If you stop having Stemetil Injection, your illness may come back and you may have other effects such as feeling or being sick, headaches, anxiety, unusual face and body movements, change in body temperature or difficulty sleeping. Your doctor will gradually stop your medicine to prevent these effects happening.

4. Possible side effects

Like all medicines, Stemetil 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, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have an unusually pale complexion, sweating, high temperature, fast heartbeat, stiff muscles, fast breathing and feel confused, drowsy or agitated. These could be signs of a serious side effect called 'neuroleptic malignant syndrome'
- You have frequent infections such as fever, sore throat or mouth ulcers. These could be signs of a blood problem called leucopenia
- You may get infections more easily than usual. This could be because of a blood disorder (agranulocytosis)
- You have yellowing of your skin or eyes (jaundice). These could be signs of liver problems
- You have a very fast, uneven or forceful heartbeats (palpitations) and experience breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain
- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through the blood vessels to the lungs causing chest pain and difficulty in breathing.
- You have rigid or stiff muscles, trembling or shaking, difficulty moving, or loss of muscle power
- You have an urge to move that you cannot control, or you have repetitive, involuntary movements, such as grimacing and eye blinking
- Feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate anti-diuretic hormone secretion (SIADH)
- You have a fit (seizure)
- Dizziness

Tell your doctor as soon as possible if you have any of the following side effects:

- Breathing problems
- Changes in your skin or eye colour after having Stemetil Injection for a long period of time
- Problems with your eyesight after having Stemetil Injection for a long period of time
- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure)
- Excessive thirst, hunger, urination or tiredness which could be signs of high blood sugar
- Feeling tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days

- Abnormal production of breast milk in men and women
- Breast enlargement in men
- Loss of menstrual periods
- Difficulty in getting or maintaining an erection (impotence)
- Persistent and painful erection of penis (priapism)
- Problems with ejaculation
- Difficulty sleeping (insomnia)

- Feeling restless or agitated
- Dry mouth
- Constipation
- Intestinal blockage
- Urinary problems including passing less urine than is normal for you
- Your skin being more sensitive to the sun than usual
- Stuffy nose
- Skin rashes
- Skin redness, swelling and itching from touching the medicine

Sudden Death - in elderly people with dementia and patients with heart rhythm disorders, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

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).

Eosinophilia which is an increase in the number of eosinophils (a type of white blood cells) found in a blood test.

Additional side effects in children

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

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 HPRA Pharmacovigilance, Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Stemetil Injection

This medicine will be kept by your doctor or nurse out of the sight and reach of children.

Do not use Stemetil Injection after the expiry date which is stated on the label and carton, after EXP. The expiry date refers to the last day of that month.

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

Use immediately after opening the ampoule. Discard any remaining solution. Discoloured solution should not be used.

Do not throw away any medicines via wastewater. These measures will help to protect the environment.

6. Contents of the pack and other information

What Stemetil Injection contains

- Each 1 ml of Stemetil Injection contains 12.5 mg of the active substance, prochlorperazine mesilate.
- The other ingredients are sodium sulphite anhydrous (E221), sodium metabisulphite (E223), sodium chloride, ethanolamine and water for injection.

What Stemetil Injection looks like and contents of the pack

Stemetil Injection is a clear, bright solution, almost colourless or not more than very pale yellow, contained in a printed ring coded ampoule.

Stemetil Injection is available in packs containing 10 x 1 ml ampoules.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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