

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Stemetil 12.5 mg/ml Injection

prochlorperazine mesilate



Is this leaflet hard to see or read?

Phone 0845 372 7101 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, nurse or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, nurse 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 have 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:

- Stop you feeling sick (nausea) or being sick (vomiting).
- Treat schizophrenia.
- Treat overactive behaviour or thoughts (mania).

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



Do not have Stemetil Injection if:

- X** You are allergic (hypersensitive) to prochlorperazine mesilate or any of the other ingredients of Stemetil Injection (listed in section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- X** 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, nurse or pharmacist before having Stemetil Injection if:
 - ▲ You are allergic to phenothiazine medicines such as chlorpromazine.

- ▲ You have heart problems or a family history of heart problems.
- ▲ You have ever had a stroke.
- ▲ 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 or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- ▲ 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 underweight.
- ▲ You have a history of alcohol problems.
- ▲ You are elderly (65 years of age or older).
- ▲ You are diabetic or have high levels of sugar in your blood (hyperglycaemia). Your doctor may want to monitor you more closely.

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



Other medicines and Stemetil Injection

Tell your doctor, nurse or pharmacist if you are taking, 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 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).
- 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.
- Desferrioxamine – 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

Do not have Stemetil Injection if:

- You are pregnant, think you may be pregnant or are planning to have a baby.
- You are breast-feeding or planning to breast-feed.

The following symptoms may occur in newborn babies, of mothers that have used Stemetil Injection 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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, nurse or pharmacist for advice before taking this medicine.



Driving and using machines

You may feel sleepy after having this medicine. If this happens, do not drive or use any tools or machines.

Stemetil Injection contains

- **Sodium:** This medicine contains 2.91mg of sodium per injection. This should be taken into consideration by people on a controlled sodium diet.
- **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:

Turn Over

Schizophrenia and overactive behaviour or thoughts (mania):

Adults: 12.5 - 25 mg two or three times a day. You will be given injections until you are able to take Stemetil Tablets or syrup.

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 and adolescents

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 or difficulty sleeping. Your doctor will gradually stop your medicine to prevent these effects happening.

Exposure to sunlight

Stemetil Injection can cause your skin to be more sensitive to sunlight. You should avoid exposure to direct sunlight while having this medicine.

Tests

Your doctor may do regular tests while you are having this medicine. These might include blood tests 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, nurse or pharmacist.

4. Possible side effects

Like all medicines, this medicine 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 very fast, uneven or forceful heartbeats (palpitations) and experience breathing problems such as wheezing, shortness of breath, tightness in the chest and chest pain.
- You have 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. If you notice any of these symptoms seek medical advice immediately.
- You have rigid or stiff muscles, trembling or shaking, unusual eye movements (including rolling of the eyes), difficulty moving, or loss of muscle power.

Tell your doctor or nurse 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).
- You have fits (convulsions).

- 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 (hyponatraemia).
- 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).
- Passing large amounts of urine, excessive thirst and having a dry mouth or skin. You may be more likely to get infections, such as thrush. This could be due to too much sugar in your blood (hyperglycaemia).

Tell your doctor, nurse 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)
- Difficulty sleeping (insomnia)
- Feeling restless or agitated
- Dry mouth
- Your skin being more sensitive to the sun than usual
- Stuffy nose
- Skin rashes
- Skin redness, swelling and itching from touching the medicine

As with other phenothiazine medicines, there have been very rare reports of sudden death with Stemetil Injection. These are possibly caused by heart problems.

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.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. 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 Stemetil Injection

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

Do not use this medicine after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Keep the ampoules 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 throw away medicines you no longer use. These measures will help 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 powder (E223), sodium chloride, ethanalamine and water for injection.

What Stemetil Injection looks like and contents of the pack

Stemetil Injection is a colourless sterile solution. Stemetil Injection is available in packs containing 10 x 1 ml ampoules or 10 x 2 ml ampoules. Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS, UK
Tel: 0845 372 7101
email: uk-medicalinformation@sanofi.com

Manufacturer

SANOFI S.P.A.
Via Valcanello, 4
03012 Anagni (FR)
ITALY

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, nurse or pharmacist.

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