

PACKAGE LEAFLET: INFORMATION FOR THE USER

Stemetil® 5mg Tablets

(prochlorperazine maleate)

Read all of this leaflet carefully before you start taking 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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Stemetil 5mg Tablets but will be referred to as Stemetil throughout this leaflet.

What is in this leaflet:

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

1. What Stemetil is and what it is used for



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

Stemetil can be used to:

- Treat balance problems or dizziness (vertigo). This includes problems of the inner ear such as 'Meniere's Syndrome' or 'labyrinthitis'.
- 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



Do not take Stemetil if:

- x You are allergic (hypersensitive) to prochlorperazine, phenothiazine medicines such as chlorpromazine or any of the other ingredients of Stemetil (listed in section 6).

Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.



Warnings and precautions

Talk to your doctor or pharmacist before taking Stemetil if:

- ▲ 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 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 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 are elderly (65 years of age or older).
- ▲ The person is a child. This is because children may develop unusual face and body movements (dystonic reactions).
- ▲ 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 or pharmacist before taking Stemetil.

Tests

Your doctor may do regular tests while you are taking this medicine. These might include blood tests and an ECG to check your heart is working properly.



Other medicines and Stemetil

Tell your doctor 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 can affect the way some other medicines work. Also some medicines can affect the way Stemetil 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, including amitriptyline.
- 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).
- Medicines for indigestion and heartburn (antacids).
- 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 with alcohol

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

Pregnancy and breast-feeding

Do not take Stemetil 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 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 or pharmacist for advice before taking this medicine.



Driving and using machines

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

Stemetil contains lactose

This medicine contains lactose, a type of sugar. If you have been told by your doctor that you cannot tolerate some sugars, talk to your doctor before taking Stemetil.

3. How to take Stemetil

Always take Stemetil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Do not give to children under 1 year of age or who weigh less than 10kg.
- You should not let the tablets touch your skin for very long, as you may get skin redness, swelling and itching (contact skin sensitisation).
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

Adults

Treatment of balance problems or dizziness (Vertigo):

- The usual dose is 5mg three times each day.
- This may be increased to a total daily dose of 30mg each day.
- After several weeks treatment, your doctor may decide to gradually lower your daily dose to 5-10mg each day.

Stopping you feeling sick or being sick:

- The usual dose is 5mg or 10mg.
- This may be taken two or three times each day.

Treatment of feeling sick or being sick:

- To begin with you will usually take 20mg.
- This may be followed by 10mg two hours later.

Treatment of schizophrenia and overactive behaviour or thoughts (mania):

- The starting dose is usually 12.5mg twice each day for seven days.
- Your doctor may increase your dose up to a total daily dose of 75-100mg each day.
- After several weeks of treatment, your doctor may then lower your dose to a total daily dose of 25-50mg each day.

Short-term treatment of anxiety:

- The starting dose will be 15-20mg each day in divided doses.
- Your doctor may then increase your dose to a total daily dose of 40mg each day.

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 (over 1 year of age and weighing more than 10kg)

Stopping your child feeling sick or being sick:

- Your doctor will decide the dose according your child's weight.
- A dose of 0.25mg for each kilogram of your child's weight is usually given.
- This dose may be given two or three times a day.

If you take more Stemetil than you should

If you take more Stemetil than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. Taking too much Stemetil may cause symptoms such as feeling 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 forget to take Stemetil

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Stemetil

Keep taking Stemetil until your doctor tells you to stop. Do not stop taking Stemetil just because you feel better. If you stop, 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 can cause your skin to be more sensitive to sunlight. You should avoid exposure to direct sunlight while taking this medicine.

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

4. Possible side effects

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

Stop taking Stemetil and see a doctor or go to a hospital straight away if:

- You have an **allergic reaction**. This can occur immediately after drug administration and may be life-threatening. Symptoms 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.
- 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 as soon as possible if you have any of the following side effects:

- Breathing problems.
- Changes in your skin or eye colour after taking Stemetil for a long period of time.
- Problems with your eyesight after taking Stemetil 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 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. 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, 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 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

Keep this medicine in a safe place where children cannot see or reach it.

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

Stemetil should be stored below 25°C and protected from strong light. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment. If the tablets become discoloured or show signs of any deterioration, you should consult your pharmacist who will advise you what to do.

6. Contents of the pack and other information

What Stemetil contain

Your medicine is called Stemetil 5mg Tablets. It contains 5mg of the active ingredient, prochlorperazine maleate. The other ingredients are lactose, maize starch, magnesium stearate and colloidal silicon dioxide.

What Stemetil look like and contents of the pack

Stemetil 5mg Tablets are pale cream, round tablets marked 'STEMETIL 5' on one side and plain on the reverse.

Stemetil 5mg Tablets are available as blister packs of 100 tablets

Manufactured by: Famar Health Care Services Madrid S.A.U., Alcorcon, Spain.

Procured from within the EU and repackaged by the Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Stemetil® 5mg Tablets; PL 18799/2514

Leaflet date: 22.03.2024

POM

Stemetil is the registered trademark of Sanofi.

**Blind or partially sighted?
Is this leaflet hard to see or read?
Call 0208 515 3763 to obtain the
leaflet in a format suitable for you.**