

STEMETIL® 5mg TABLETS
(prochlorperazine maleate)
Patient Information Leaflet

This product is known by the above name but will be referred to as Stemetil Tablets throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine

- 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

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1. What Stemetil Tablets are and what they are used for

Stemetil Tablets contain 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 Tablets 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. Before you take Stemetil Tablets

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to prochlorperazine maleate or any of the other ingredients of Stemetil Tablets (listed in Section 6 overleaf)
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue

Take special care with Stemetil Tablets

Check with your doctor or pharmacist before taking your medicine 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 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 Tablets.

Taking other medicines

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

Taking Stemetil Tablets with food and drink

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

Pregnancy and breast-feeding

Do not take Stemetil Tablets if:

- You are pregnant, might become pregnant or think you might be pregnant
- You are breast-feeding or planning to breast-feed

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

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of Stemetil Tablets

- **Lactose.** This medicine contains lactose, a type of sugar. If you have been told by your doctor that you can not tolerate some sugars, talk to your doctor before taking Stemetil Tablets

3. How to take Stemetil Tablets

Always take Stemetil Tablets 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 10 kg
- 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 5 mg three times each day
- This may be increased to a total daily dose of 30 mg each day
- After several weeks treatment, your doctor may decide to gradually lower your daily dose to 5 to 10 mg each day

Stopping you feeling sick or being sick:

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

Treatment of feeling sick or being sick:

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

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

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

Short-term treatment of anxiety:

- The starting dose will be 15 to 20 mg each day in divided doses
- Your doctor may then increase your dose to a total daily dose of 40 mg 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 10 kg):**Stopping your child feeling sick or being sick:**

- Your doctor will decide the dose according your child's weight
- A dose of 0.25 mg 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 Tablets than you should

If you take more Stemetil Tablets 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 Tablets 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 Tablets

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 Tablets

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

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.

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

4. Possible side effects

Like all medicines, Stemetil Tablets can cause side effects, although not everybody gets them.

Stop taking Stemetil Tablets and see a doctor or go to a hospital 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 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 Tablets for a long period of time
- Problems with your eyesight after taking Stemetil Tablets for a long period of time
- Feeling dizzy, lightheaded or faint when you stand or sit up quickly (due to low blood pressure)
- 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

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.

United Kingdom

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

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

5. How to store Stemetil Tablets

- Keep this medicine in a safe place where children cannot see or reach it.
- Do not use Stemetil Tablets 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 Tablets 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. Further information**What Stemetil Tablets 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 Tablets 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

Product Licence holder and Manufacturer

POM

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