

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. 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

What is in this leaflet:

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

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'
- 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 Tablets

Do not take this medicine and tell your doctor if:

- X You are allergic (hypersensitive) to prochlorperazine maleate, phenothiazine medicines such as chlorpromazine or any of the other ingredients of Stemetil Tablets (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
- X You have liver problems

Warnings and Precautions

If you experience an allergic reaction (see section 4 “Possible side effects”) contact your doctor or other healthcare professional immediately or go to the nearest hospital emergency room right away.

Take special care with Stemetil Tablets.

Check with your doctor or pharmacist before taking your medicine 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 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)
- The patient is a child. This is because children may develop unusual face and body movements (dystonic reactions)
- The patient is an infant less than 1 year of age

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

Talk to your doctor or pharmacist when you are taking Stemetil Tablets 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 check-ups 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 Tablets

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 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 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 Tablets with alcohol

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

Stemetil Tablets should be avoided during pregnancy and breast-feeding. 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 Tablets can pass into breast milk and affect your baby (see section 4).

Driving and using machines

Stemetil Tablets cause anticholinergic effects on the eye (disturbances in adapting the size of the eye pupil to light), drowsiness, blurred vision or dizziness, especially when you start treatment. This may affect your ability to react. You should keep this in mind in cases when increased attention is required. Do not drive or operate any tools or machines when you start treatment.

Stemetil Tablets contain 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 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
- 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), or feeling sick or being sick:

- The usual dose is 10 to 40 mg each day in divided doses

Treatment of schizophrenia and other psychotic disorders:

- The usual dose is 75 to 100 mg each day in divided doses

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 is not recommended for use in children.

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, 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.

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 leukopenia
- 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
- You have 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 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)
- 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 Tablets 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 any 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 Tablets

Keep this medicine out of the sight and reach of children.

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

Do not store above 30°C. Store in the original container 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 Tablets contains

- Each tablet contains 5 mg of the active substance, prochlorperazine maleate.
- The other ingredients are lactose monohydrate, maize starch, colloidal anhydrous silica and magnesium stearate

What Stemetil Tablets look like and contents of the pack

Stemetil Tablets are off-white to pale cream coloured circular tablets. The tablets marked “STEMETIL” and “5” on one side. Stemetil Tablets are available in bottles containing 250 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Atnahs Pharma Netherlands B.V.
Copenhagen Towers
Ørestads Boulevard 108, 5.tv
DK-2300 København S
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Manufacturer

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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.

This leaflet was last revised in 05/2024