PATIENT INFORMATION LEAFLET

Prochlorperazine Tablets BP 5 mg & 25 mg

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE
KEEP THIS LEAFLET UNTIL YOU HAVE FINISHED ALL THE PRESCRIBED COURSE OF PROCHLORPERAZINE
IF YOU HAVE ANY QUESTIONS CONCERNING YOUR MEDICINE ASK YOUR DOCTOR OR PHARMACIST FOR MORE INFORMATION

What is in your medicine?

The name of this medicine is Prochlorperazine.

Each tablet contains either Prochlorperazine Maleate BP 5 mg or Prochlorperazine Maleate BP 25 mg, together with: Lactose, maize starch, pre-gelatinised maize starch, sodium starch glycollate, sucrose and magnesium stearate.

Prochlorperazine Tablets BP 5 mg are round, white tablets, available in containers of 28, 30, 56, 60, 84, 90, 100, 500 and 1,000. The tablets are also available in blister packs of 28 and 84 tablets.

Prochlorperazine Tablets BP 25 mg are round, white tablets with a score-line on one side, available in packs of 100 and 500 tablets, and in blister packs of 28 and 84 tablets.

The Manufacturer is: Meridian Healthcare (UK) Ltd, 208-214 York Road, London SW11 3SD.

The Product Licence holder is: Chelonia Healthcare Ltd, 11 Boumpoulinas. Nicosia P.C 1060. Cyprus.

How does Prochlorperazine work?

Prochlorperazine belongs to a group of medicines, the pheno- thiazines that act on the Central Nervous System (C.N.S.).

Why have you been prescribed Prochlorperazine?

In adults Prochlorperazine is used for the prevention and treatment of nausea and vomiting. The medicine is also used for the treatment of vertigo (dizziness) and Meniere's syndrome (falling to one side).

Prochlorperazine is used as an aid in the short-term management of anxiety and for the treatment of schizophrenia and other mental (psychotic) disorders.

In children, Prochlorperazine is used for the prevention and treatment of nausea and vomiting.

If you are not sure why you have been prescribed Prochlorperazine, then please ask your doctor.

Check before you take these tablets

Before taking this medicine, tell your doctor if you have ever had any unusual or allergic reactions to Prochlorperazine, or any of the other ingredients, or other phenothiazine medicines. Also tell your doctor or pharmacist if you are allergic to any other substances such as foods, preservatives or dyes.

The presence of other medical problems may affect the use of this medicine. Make sure, therefore, to tell your doctor if you have any other medical problems, especially:

- Parkinson's disease
- Any liver or kidney problems for which you have or are receiving treatment.
- Epilepsy
- Reduced function of your thyroid gland.
- Myasthenia gravis (muscle weakness particularly after exercise).
- Enlargement of the prostate gland.
- Phaeochromocytoma (a tumor of the medulla of the adrenal gland, leading to elevated blood pressure).
- Glaucoma (raised eyeball pressure).
- You or someone else in your family has a history of blood clots, as medicines like Prochloperazine have been associated with formation of blood clots.

Use in pregnancy and breast-feeding

It is important that you tell your doctor if you are pregnant, likely to become pregnant, or are breast-feeding.

Do not use this medicine during pregnancy, unless your doctor considers it essential.

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

Because this medicine may pass into the breast milk, its use should be avoided during breast feeding.

Can you drive while taking Prochlorperazine?

Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert. Please remember that alcohol may intensify these effects and should be avoided during treatment.

Can you take Prochlorperazine with other medicines?

You can take these tablets with other medicines, but there are some medicines which can interfere with Prochlorperazine tablets. It is very important to tell you doctor or pharmacist about all the medicines which you are taking, whether prescribed by your doctor or bought without a prescription from the pharmacy or elsewhere. This includes medicines such as amphetamines, adrenaline, clonidine (used to treat migraine and high blood pressure), antacids (used to reduce stomach acid), lithium and treatments for raised blood pressure, diabetes (raised blood sugar) and Parkinson's disease.

This medicine will add to the effects of alcohol, and other medicines that tend to cause drowsiness such as anti-histamines (medicines for hay-fever and other allergies), sedatives such as barbiturates (used to treat depression), tranquillisers (for anxiety), medicines to help you sleep and pain relieving medicines.

When and how to take Prochlorperazine

Take this medicine by mouth and only in the doses

prescribed by your doctor. Do not take more of it, and do not take it more often or for a longer time than your doctor has ordered.
Your doctor will prescribe the lowest dose necessary to control your symptoms.

Usual dosages stated below:

Adults:
Prevention of nausea and vomiting: 5-10 mg two or three times a day. Treatment of nausea and vomiting: 20 mg followed if necessary by 10 mg two hours later.
Vertigo and Meniere's syndrome: 5 mg three times daily, increased if necessary to 30 mg daily. Dosage may be reduced gradually to 5-10 mg daily.
Aid in the short-term management of anxiety: Initially 15-20 mg daily in divided doses. This may be increased if necessary to a maximum of 40 mg daily in divided doses.
Schizophrenia and other psychotic (mental) disorders: The usual dose is 12.5 mg twice daily for 7 days. The dose is then increased by 12.5 mg at 4-7 day intervals until it has a satisfactory effect. After you have been on an effective dose for some weeks, your doctor may advise you to try to reduce the dosage.

Children:
For the prevention and treatment of nausea and vomiting; the dosage will depend on the child's bodyweight and will be calculated on the basis of 25 micrograms per kilo bodyweight two or three times a day. Prochlorperazine is not recommended for children weighing less than 10 kilograms.

Elderly:
Elderly patients with mental disorders should be started on a lower dose of Prochlorperazine. It should be used with caution during very hot or very cold weather to reduce the risk of an extreme rise or fall in body temperature.

What to do if too many tablets are taken at the same time
If you think you may have taken an overdose of this medicine, obtain emergency help at once at your nearest hospital casualty department or doctor. Tell the doctor in charge, or the nurse or pharmacist, that you are taking this medicine, and take any remaining tablets in their original container with you so that they may be identified.

What if you miss a dose?
If you miss a dose, skip the missed dose and go back to your regular dosage schedule. Do not take two doses at once.
If you feel that this medicine is not working as well after you have taken it for a short time (1 week) do not increase the dose, instead check with your doctor.

What side effects can Prochlorperazine cause?
Along with its needed effects the medicine may cause some unwanted effects:
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.
Nasal stuffiness, dry mouth, insomnia, agitation, dizziness when standing from a lying or sitting position, changes in heart rate, slowing of breathing in certain individuals.
Abnormal movement, tremors and muscle stiffness, and, usually in young patients, an inability to control certain muscles of the body such as tongue, mouth, arms and legs. You may experience extreme restlessness or agitation. These symptoms usually disappear after treatment with prochlorperazine is discontinued.
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 breathing.
A combination of high-temperature, pale complexion, muscle stiffness and changes in levels of alertness are symptoms of a serious condition called 'neuroleptic malignant syndrome'. If these symptoms develop, you should inform your doctor immediately.
After weeks or months of treatment it is possible that uncontrolled shaking of the hands or limbs and muscle stiffness may occur.
Disorders of the blood may occur during prolonged treatment or with high doses. If you develop a fever or experience an unusually bad sore throat or bruising, this could be a symptom of a blood disorder and you should tell your doctor immediately.
Jaundice (yellowing of the skin and whites of the eyes) may occur, sometimes preceded a sudden onset of fever, 1-3 weeks after the start of treatment. If you develop jaundice, stop the treatment and inform your doctor immediately.
In sunny weather the skin may become sensitive to sunlight, therefore direct exposure to sunlight should be avoided. Although never reported with prochlorperazine, it is possible that visual changes and a greyish discoloration of exposed skin may develop, but only after continuous long term use.
Swollen breasts can occasionally occur in men, but only after long term use. Impotence can also sometimes occur. Unusual breast milk production and absence of menstrual periods can sometimes occur in women.
Do not crush the tablets or handle them more than you need to because you may develop a skin reaction.
If you experience any of the above reactions or side effects, or notice anything unusual which you are worried about, consult your doctor.

Storing your medicine
You must keep the medicine in a safe place where children cannot get it. Your medicine could harm them.
Keep your medicine in a dry place and store below 25ºC. Keep the tablets in the container in which they were given to you. Protect from light.
If your doctor tells you to stop the treatment, return any remaining tablets to the pharmacist. Only keep the medicine if the doctor tells you to.
On the label you will find the words "Expiry Date" followed by numbers indicating the day, month and year. This is the date when the medicine is no longer fit for use. Do not use the medicine after this date, but return it to your doctor or

pharmacist.

A reminder

REMEMBER this medicine is for you. Never give it to someone else, even if their symptoms are the same as yours.

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

Product Licence no's:
5 mg - PL 33414/0083
25 mg - PL 33414/0084

This leaflet was revised in November 2011