

PACKAGE LEAFLET: INFORMATION FOR THE USER

PROCHLORPERAZINE

5 mg TABLETS

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.

WHAT IS IN THIS LEAFLET

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

1. WHAT PROCHLORPERAZINE IS AND WHAT IT IS USED FOR

Prochlorperazine belongs to a group of medicines called phenothiazines. It can be used for:

- preventing and treating nausea, vomiting and migraine
- vertigo (dizziness or spinning) due to a variety of causes including diseases of the inner ear such as Meniere's syndrome or labyrinthitis
- **short-term** relief of severe anxiety
- mental health problems such as schizophrenia or mania (unusual behaviour due to over-excitement).

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROCHLORPERAZINE

Do not take Prochlorperazine if you:

- are allergic to prochlorperazine, any of the other ingredients in the tablets (listed in section 6 of this leaflet) or to other phenothiazines
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Do not give Prochlorperazine to patients in a coma (a state of unconsciousness).

Warnings and precautions

Tell your doctor **before** you take this medicine if:

- you have any problems with your heart, liver or kidneys
- you have ever had a stroke
- you have severe breathing problems
- you have or have had yellowing of the skin or whites of the eyes (jaundice)
- you suffer from epilepsy, Parkinson's disease, dementia, depression, an eating disorder or alcohol and drug abuse
- you suffer from high blood pressure due to a tumour near the kidneys (phaeochromocytoma)
- you have an underactive thyroid gland, an enlarged prostate gland, muscle weakness (myasthenia gravis), increased eyeball pressure (glaucoma) or sensitivity to sunlight
- you are elderly and suffer from a fall in blood pressure on standing up, which causes dizziness or fainting or if you suffer from a rise or fall in body temperature in very hot or very cold weather
- you have a blood disorder including a low white blood cell count. **Regular blood tests may be needed if you have unexplained infections or fever**
- you have low blood levels of calcium, magnesium or potassium
- 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
- 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.

Other medicines and Prochlorperazine

Tell your doctor or pharmacist if you are taking or have recently taken or might take **any** other medicines, even medicines bought without a prescription.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines, as they **may affect how Prochlorperazine tablets work**:

- medicines to treat depression including amitriptyline or mental health problems such as lithium or pimozide
- medicines to treat anxiety, difficulty sleeping or daytime sleepiness
- amphetamine or atomoxetine to treat Attention Deficit Hyperactive Disorder (ADHD)
- memantine to treat Alzheimer's disease
- medicines to treat Parkinson's disease such as amantadine or levodopa
- medicines for epilepsy such as carbamazepine, ethosuximide or phenytoin
- tetrabenazine to treat movement disorders
- metoclopramide for nausea and vomiting
- medicines to relieve pain such as tramadol or general anaesthetics
- medicines to treat high blood pressure such as clonidine, guanethidine or minoxidil
- medicines to treat irregular heartbeat such as amiodarone, disopyramide or sotalol
- medicines to treat diabetes
- medicines to increase urine production
- medicines to treat cancer
- antibiotics like moxifloxacin to treat bacterial infections or ritonavir to treat viral infections
- artemether and lumefantrine to treat malaria or pentamidine isetionate to treat lung infections
- desferrioxamine to treat iron poisoning
- antihistamines to treat hayfever or other allergies
- adrenaline to treat allergic reactions or cardiac arrest
- medicines to treat bladder or gut problems
- cimetidine to treat stomach ulcers
- antacids to treat indigestion or heartburn
- kaolin to treat diarrhoea
- sibutramine for weight loss
- anticholinergic medicines – includes some medicines used for irritable bowel syndrome, asthma or incontinence.

Prochlorperazine with alcohol

Do not drink alcohol when taking this medicine. This is because alcohol can add to the effects of Prochlorperazine tablets and can cause serious breathing difficulties.

Pregnancy and breast-feeding

Do not take Prochlorperazine tablets if you are pregnant, think you may be pregnant or are planning a pregnancy or you are breast-feeding or planning to breast-feed.

The following symptoms may occur in new-born 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.

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

Prochlorperazine tablets can make you feel drowsy or less alert. If affected do not drive or operate machinery. **Do not drink alcohol** as it can increase these effects.

Prochlorperazine contains Lactose

This medicine contains lactose, a type of sugar. If you know or have been told by your doctor that you have an intolerance to lactose or other sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE PROCHLORPERAZINE

Always take Prochlorperazine 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 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).

Dosage

Your doctor will decide your dose and length of treatment, as it depends on your condition. If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

DO NOT STOP taking the tablets until your doctor tells you to.

Adults:

Prevention of nausea and vomiting: Typical dose is 5-10 mg two or three times a day.

Treatment of nausea and vomiting: Typical dose is 20 mg to start with, followed if necessary by 10 mg two hours later.

Vertigo and Meniere's syndrome: Typical dose is 5 mg three times a day, increased if necessary to a maximum of 30 mg daily. After several weeks the dosage may be reduced gradually to 5-10 mg a day.

Short-term relief of severe anxiety: Typical dose is 15-20 mg a day in divided doses, increased if necessary to a maximum of 40 mg in divided doses.

Mental health problems: Typical dose starts with 12.5 mg twice a day for seven days, followed by gradual increases of 12.5 mg a day at four to seven day intervals, to a maximum of 75-100 mg a day. After several weeks the dosage may be reduced gradually to 25-50 mg a day.

Elderly: Require smaller doses. Follow your doctor's advice. Care should also be taken 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):

Prevention and treatment of nausea and vomiting: Your child will be given a dose depending on their bodyweight. Typical dose is 0.25 mg/kg two to three times a day.

If you take more Prochlorperazine than you should

Contact your doctor or pharmacist immediately; or go to a hospital casualty department straight away. Show them the package. This is so the doctor knows what you have taken. Taking too much prochlorperazine 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 Prochlorperazine

Don't worry, just take your next scheduled dose at the correct time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Prochlorperazine

Keep taking prochlorperazine until your doctor tells you to stop. Do not stop taking prochlorperazine 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.

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

4. POSSIBLE SIDE EFFECTS

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

STOP TAKING this medicine 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.
- 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'.
- have frequent infections such as fever, sore throat, or mouth ulcers. These could be signs of a blood problem called leucopenia.
- may get infections more easily than usual. This could be because of a blood disorder (agranulocytosis).
- have yellowing of your skin or eyes (jaundice). These could be signs of liver problems.
- 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.
- 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.
- 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 prochlorperazine for a long period of time.
- Problems with your eyesight after taking prochlorperazine 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 Prochlorperazine. 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 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 PROCHLORPERAZINE

Keep out of the sight and reach of children.

Do not store above 25°C. Store in the original package or container and keep the container tightly closed.

Do not use these tablets after the expiry date, which is stated on the package or container. The expiry date refers to the last day of that month.

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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Prochlorperazine contains

The active ingredient in Prochlorperazine 5 mg tablets is prochlorperazine maleate. The other ingredients are lactose, maize starch, pregelatinised maize starch, sodium starch glycollate, sucrose and magnesium stearate.

What Prochlorperazine looks like and contents of the pack

Prochlorperazine 5 mg tablets are round white tablets with the marking MP13 on one side.

The tablets come in blister packs of 28 and 84 tablets and containers of 28, 30, 56, 60, 84, 90, 100, 500 and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Genethics Europe Limited,
41 – 43 Klimentos, Klimentos Tower, Nicosia 1061, Cyprus

Manufacturer

Haupt Pharma Berlin GmbH,
Gradestraße 13, Moosrosenstraße 5 and Britzer Damm 120,
12347 Berlin, Germany

For more information about this product, please contact the Marketing Authorisation Holder.

This leaflet was last revised in 07/2020

GE0009/O/PIL/GE2