1. **WHAT PROCHLORPERAZINE IS 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. **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
- suffer from depression of the central nervous system, which may cause problems with your vision, coordination, breathing or heart rate
- suffer from high blood pressure due to a tumour near the kidneys (phaeochromocytoma).

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

Take special care with Prochlorperazine

Tell your doctor before you take this medicine if you:

- have any problems with your heart, liver or kidneys
- have severe breathing problems
- have or have had yellowing of the skin or whites of the eyes (jaundice)
- suffer from epilepsy, Parkinson’s disease, depression, an eating disorder or alcohol and drug abuse
- have an underactive thyroid gland, an enlarged prostate gland, muscle weakness (myasthenia gravis), increased eyeball pressure (glaucoma) or sensitivity to sunlight
- 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
- have a blood disorder including a low white blood cell count. Regular blood tests may be needed if you have unexplained infections or fever
- have low blood levels of calcium, magnesium or potassium
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken, 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 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

AVOID ALCOHOL when taking this medicine.

If you go into hospital or have treatment for other conditions, tell the doctor that you are taking Prochlorperazine.

Pregnancy and breast-feeding
Do not take Prochlorperazine tablets if you are pregnant, planning a pregnancy or breast-feeding, unless your doctor has advised you to take them.
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.

Driving and using machines
Prochlorperazine tablets can make you feel drowsy or less alert. If affected do not drive or operate machinery. AVOID ALCOHOL as it can increase these effects.

Important information about some of the ingredients of Prochlorperazine
If you know 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. Take this medicine by mouth.

Dosage
Your doctor will decide your dose and length of treatment, as it depends on your condition.

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.

Children over 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. Do not give to children weighing less than 10 kg.

If you take more Prochlorperazine than you should Contact your doctor or pharmacist immediately. Show them the package.

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 the one you have missed.

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

STOP TAKING this medicine and see a doctor straight away if you have:
• a condition called Neuroleptic Malignant Syndrome, which causes fever, sweating, pale skin, muscle stiffness, difficulty passing urine, fast heart beat or changes in alertness or blood pressure
• 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.

Common side effects (these may depend on the dose, length of treatment or response to the medicine):
• restlessness, shaking (tremor) or jerky movements
• uncontrollable, repetitive movements of the tongue, face, jaw, arms, legs or entire body
• a fall in blood pressure on standing up, which causes dizziness or fainting
• a rise or fall in body temperature in very hot or very cold weather.

Rare side effects:
• blood disorders causing unexplained bleeding, bruising, sore throat, general illness or fever.

**Very rare side effects:**
• high blood pressure, fast or irregular heart beat
• jaundice
• eye problems including glaucoma
• skin sensitivity when the drug is placed in contact with the skin, rashes, sensitivity to sunlight or a purple tint to the skin and eyes.

**Other side effects:**
• drowsiness, dizziness, headache or confusion
• agitation, excitement, lack of interest or emotion
• fits
• difficulty sleeping (insomnia)
• blocked nose
• dry mouth
• blurred vision
• constipation or difficulty passing urine
• stomach or gut problems
• breathing problems
• weight gain
• loss of periods in women, breast milk production, development of breasts in men or problems maintaining an erection

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.

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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5. HOW TO STORE PROCHLORPERAZINE

Keep out of the reach and sight 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.

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6. FURTHER 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.

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