

## Package Leaflet: Information for the User Prochlorperazine 5mg 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 tablets are and what they are used for
2. What you need to know before you take Prochlorperazine tablets
3. How to take Prochlorperazine tablets
4. Possible side effects
5. How to store Prochlorperazine Tablets
6. Contents of the pack and other information

### 1. What Prochlorperazine tablets are and what they are used for

Prochlorperazine tablets belong to a group of drugs known as phenothiazines, which act on the central nervous system. In adults they are used in the treatment of **vertigo (dizziness)** and **Meniere's syndrome** (falling to one side), the short term treatment of **anxiety** and to treat **schizophrenia** and other **mental (psychotic) disorders**. The tablets may also be used for the prevention and treatment of **nausea and vomiting** in adults and children.

### 2. What you need to know before you take Prochlorperazine tablets

**Do not take Prochlorperazine tablets** if you:

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Prochlorperazine tablets if:

- You have heart problems such as **heart failure** or **prolonged QT** (ECG change which increases the risk of potentially serious cardiac arrhythmias) or have a family history of heart problems
- You have ever had a **stroke**
- You have **liver or kidney** problems, history of **jaundice**
- You have **epilepsy** or have ever had **fits (seizures)**
- You have or someone in the family has a **history of blood clots**, as medicines like these have been associated with the formation of blood clots
- You have **Parkinson's** disease
- You have **thyroid problems** such as **hypothyroidism** (reduced activity of the thyroid gland)
- You have **dementia**
- You have **depression**
- You have **myasthenia gravis** (condition causing weak muscles)
- You have or ever had **glaucoma** (raised eyeball pressure)
- 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 a **tumour** on your adrenal gland called '**phaeochromocytoma**'
- You have an enlarged **prostate gland**. This means you may have problems when passing water (urine)
- 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 blood sugar (**hyperglycaemia**). Your doctor may want to monitor you more closely

#### Other medicines and Prochlorperazine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription (as they may alter the effects of this medicine) especially:

- Medicines to help you sleep (sedatives such as barbiturates - sedative effect is intensified)
- 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
- Desferroxamine - used if you have too much iron in your blood
- Lithium – used for some type of mental illness
- Ritonavir (for HIV)

#### Taking Prochlorperazine Tablets with food and drink

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

#### Pregnancy and breast-feeding

Do not take Prochlorperazine 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 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. Ask your doctor or pharmacist for advice before taking any medicines if you are pregnant or breast-feeding.

#### Driving and using machines

This medicine may cause some people to become drowsy or less alert than usual. If you are affected, do not drive or operate dangerous machinery.

#### Prochlorperazine Tablets contain lactose

If a doctor has told you that you have an intolerance to some sugars, check with your doctor before taking these tablets, as they contain a type of sugar called lactose.

### 3. How to take Prochlorperazine tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You will be prescribed the lowest dose needed to control your symptoms. **Do not stop taking your medicine or change the dose** unless your doctor tells you to.

The tablets should be swallowed with a glass of water.

**Do not crush the tablets or handle them more than you need to** because you may develop a skin reaction.

#### Dose for nausea and vomiting

**Adults: Prevention of nausea and vomiting:** 5 - 10mg two or three times a day.

**Treatment of nausea and vomiting:** 20mg followed if necessary by 10mg two hours later.

#### Dose for anxiety

**Adults:** Initially 15 - 20mg daily in divided doses. This may be increased if necessary to a maximum of 40mg daily in divided doses.

**Children (over 1 year of age and weighing more than 10 kg): Prevention and treatment of nausea and vomiting:**

The dose will depend on the child's bodyweight and will be calculated on the basis of 250 micrograms per kilogram bodyweight two or three times a day.

Prochlorperazine is not recommended for children weighing less than 10 kilograms or children less than 1 year of age.

**Dose for vertigo and Meniere's syndrome:**

**Adults:** 5mg three times daily, increased if needed to 30mg daily. Dosage may be reduced gradually to 5 - 10mg daily.

**Dose for schizophrenia and other psychotic (mental) disorders:**

**Adults:** The usual dose is 12.5mg twice daily for 7 days. The dose is then increased by 12.5mg 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.

**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.

**If you take more Prochlorperazine Tablets than you should**

If you accidentally take more tablets or somebody else takes any tablets, contact a doctor or go to your nearest hospital casualty department at once. Take any remaining tablets with you and the container or packaging, so they can be identified. Taking too many Prochlorperazine 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 Prochlorperazine Tablets**

If you miss a dose, skip the missed dose and go back to your regular schedule. **Do not take a double dose** to make up for a forgotten dose.

**If you stop taking Prochlorperazine Tablets**

Keep taking Prochlorperazine Tablets until your doctor tells you to stop. Do not stop taking Prochlorperazine 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**

Prochlorperazine 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 medicine, ask your doctor or pharmacist.

**4. Possible side effects**

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

**Stop taking the tablets and see a doctor at once or go to a hospital straight away if you develop any of the following effects:**

- 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 a combination of high-temperature, pale complexion, muscle stiffness and feel confused, drowsy or agitated. These are signs of a serious condition called 'neuroleptic malignant syndrome'.
- You have frequent infections such as fever or an unusually bad sore throat, mouth ulcers or bruising. These could be symptoms of a blood disorder called leucopenia.
- You may get infections more easily than usual. This could be because of a blood disorder (agranulocytosis).
- You have yellowing of the skin and whites of the eyes (jaundice) sometimes preceded by a sudden onset of fever, 1-3 weeks after start of treatment. 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 or if you have any other unusual or worrying effects.**

- Breathing problems
- Changes in your skin or eye colour after taking Prochlorperazine Tablets continuously for long periods of time (4 – 8 years)
- Problems with your eyesight after taking Prochlorperazine 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 this 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. You can also report side effects directly via the Yellow Card Scheme at: <http://yellowcard.mhra.gov.uk/>

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

**5. How to store Prochlorperazine Tablets**

Do not store above 25°C. Store in a dry place. Keep the container tightly closed. Keep out of the sight and reach of children.

**Do not use this medicine after the expiry date** which is printed on the packaging. The expiry date refers to the last day of that month. If your doctor tells you to stop the treatment, return any unused tablets to your pharmacist for safe disposal. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Prochlorperazine Tablets contain**

- The active ingredient (which makes these tablets work) is prochlorperazine maleate BP. Each tablet contains 5mg prochlorperazine maleate BP.
- The tablets also contain lactose, maize starch, pre-gelatinised maize starch, sodium starch glycolate, sucrose and magnesium stearate.

**What Prochlorperazine Tablets look like and contents of the pack**

The tablets are uncoated almost white or pale buff coloured, with flat bevelled edges and are available in containers of 28, 30, 56, 60, 84, 90, 100, 500, 1000 tablets and in blister packs of 28 and 84 tablets.

**Marketing authorisation holder and manufacturer**

Dr. Reddy's Laboratories (UK) Ltd., 6 Riverview Road, Beverley, East Yorkshire, HU17 0LD.

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