

Package leaflet: Information for the user

prochlorperazine maleate 3 mg Buccal Tablets prochlorperazine maleate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or Pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.

The full name of this product is Prochlorperazine maleate 3 mg Buccal Tablets but within the leaflet it will be referred to as Prochlorperazine tablets.

What is in this leaflet

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

1. What Prochlorperazine tablets is and what it is used for

Prochlorperazine tablets are effective in treating nausea (feeling sick) and vomiting (being sick) from whatever cause. They are also used to treat migraine and dizziness due to ear problems and other causes.

Prochlorperazine tablets contain prochlorperazine maleate. Prochlorperazine belongs to a large group of drugs known as phenothiazines, which have a variety of effects.

2. What you need to know before you use Prochlorperazine tablets

You should only use Prochlorperazine tablets when your doctor prescribes them for you.

Do not use Prochlorperazine tablets:

- if you are allergic to prochlorperazine maleate or any of the other ingredients of this medicine (listed in section 6)
- if you have problems with your liver
- if you have blood problems
- if you suffer from epilepsy, Parkinson's Disease or glaucoma
- if you have problems with your prostate gland.

Warnings and precautions

Talk to your doctor before using Prochlorperazine tablets:

- if you are elderly

- If you are born with or have a family history of prolonged QT interval, or if you have acquired QT prolongation (seen on ECG, electrical recording of heart).
- If you have heart disorders or have a history of heart attack (myocardial infarction).
- If you have salt imbalance in the blood (especially low level of potassium or magnesium).
- if you are pregnant, thinking of becoming pregnant or breast feeding if you have risk factors for a blood clot or stroke such as high blood pressure, high cholesterol levels, diabetes or smoking
- if 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.
- if you have a condition called myasthenia gravis, which causes muscle weakness
- if you have AIDS.

Prochlorperazine tablets may cause you to be more sensitive to sunlight. When taking Prochlorperazine tablets it is particularly important that you should avoid exposure to direct sunlight and use sunscreen.

Other medicines and Prochlorperazine tablets

Tell your doctor if you are using, have recently used or might use any other medicines. In particular, tell your doctor or pharmacist if you are using:

- medicines known to affect the rhythm of your heart. This includes medicines used for abnormal heart rhythm (antiarrhythmics), for depression (tricyclic antidepressants) & psychiatric disorders (antipsychotics).
- Azithromycin, clarithromycin or erythromycin (antibiotics used for treating infections). Taking these medicines at the same time as Prochlorperazine maleate 3 mg Buccal Tablets may increase the chance of you getting side effects that affect your heart.
- sedatives or tranquilisers, used to help you sleep (such as diazepam and temazepam)
- antihypertensive medicines, used to treat high blood pressure (such as atenolol, propranolol or clonidine)
- anticholinergic medicines, used for conditions such as depression (such as amitriptyline and imipramine)
- anticonvulsant medicines used to prevent or treat fits such as carbamazepine and lamotrigine)
- lithium (used to treat mania and depression)
- desferrioxamine (used to treat high levels of iron in your body).
- oral anticoagulants, to help prevent blood clots (such as warfarin)
- levodopa (used to treat Parkinson's disease)

Prochlorperazine tablets with food and drink

Prochlorperazine tablets are best taken **after food**.

Do not drink alcohol when using the tablets as it may interact with medicines like Prochlorperazine.

Pregnancy and breast-feeding

Do not use Prochlorperazine Maleate 3 mg Buccal 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 tablets 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.

Experience with Prochlorperazine tablets is limited. You should therefore not take the tablets if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Prochlorperazine tablets can make you feel drowsy. Therefore, you should avoid driving or using dangerous machines until you know how the tablets affect you.

Prochlorperazine tablets contain sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using this medicinal product.

3. How to use Prochlorperazine tablet

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

The recommended dose is one or two tablets twice a day for adults and children over 12 years of age.

Prochlorperazine tablets are **not recommended** for children **under 12 years of age**.

INSTRUCTIONS FOR USE **Please read carefully before using the tablet(s)**



- Place the tablet high up along your top gum, under the upper lip either side of your mouth as indicated above. The tablet must not be swallowed whole or chewed.
- The tablet will soften and adhere to the gum. Allow it to dissolve slowly and completely - this may use between 1 and 2 hours. Most people find that after a few minutes they no longer notice the tablet.
- The tablet should not be moved about the mouth with the tongue as this will cause it to dissolve too quickly.
- If you wear dentures, the tablet may be placed in any comfortable position between your lip and gum.

The tablet(s) is best taken **after** meals.

If you use more Prochlorperazine tablets than you should

If you accidentally use too many tablets **you must** seek medical attention immediately. Show any left-over medicines or the empty packet to the doctor.

If you forget to use Prochlorperazine tablets

If you forget to use a dose do not double the dose next time. Just carry on using the medicine as the doctor has told you.

4. Possible side effects

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

Serious side effects

If you experience any of the following side effects, you should **stop using Prochlorperazine tablets and contact your doctor immediately**:

- Symptoms of an allergic reaction such as rash and swelling of the face, tongue or throat.
- A high temperature, pale complexion, muscle stiffness and changes in levels of alertness, you may have developed a serious condition called neuroleptic malignant syndrome.
- Convulsions (fits).
- Signs of infection such as shivering, headache, sweating, high temperature, flushing, a sore throat or mouth and swollen glands.
- Very fast, uneven, or forceful heartbeats (palpitations) and breathing problems such as wheezing, Shortness of breath, tightness in the chest & Chest pain.
- 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.
- Symptoms of decreased sodium concentration in the blood, such as nausea and vomiting, headache, confusion, loss of energy, restlessness, muscle weakness, spasms or cramps, seizures and coma.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients using medicines of the same type as Prochlorperazine tablets compared with those not using these medicines.

Other side effects include:

Rare: may affect up to 1 in 1,000 people

- Jaundice
- Blood problems

Very rare: may affect 1 in 10,000 people

- Breast swelling (in men as well women)
- Milk secretion from the breast which is not due to breast-feeding.
- Absence of menstrual periods.

Unknown: frequency cannot be estimated from the available data

- drowsiness
- dizziness
- dry mouth
- inability to sleep (insomnia)
- agitation
- a feeling of restlessness or anxiety that can range from mild to severe
- skin reactions
- increased sensitivity to sunlight
- low blood pressure (this makes you feel dizzy or faint, particularly when you stand up), particularly in elderly or volume depleted patients (those who have lost both water and salts from the body).
- high blood sugar level, which can cause increased thirst, a dry mouth, needing to urinate frequently, tiredness and recurrent infections such as thrush

- a condition known as cholestasis where bile cannot flow properly in the body, and can cause itchy skin, jaundice (yellowing of the skin and/or the whites of the eyes), pale stools and dark urine
- abnormal movements, tremors and muscle rigidity, and unusual movements of the face and tongue
- impotence, ejaculation problems and persistent/ painful erections
- local irritation to the gum and mouth.
- numbness of mouth
- tingling, pricking or burning of mouth
- altered or decreased ability to taste

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 Yellow Card Scheme at Website: 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 Buccal Tablet

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

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater. 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 Prochlorperazine Buccal Tablet contains

- Each buccal tablet contains 3 mg of prochlorperazine maleate.
- The other ingredients are: compressible sugar (sucrose), xanthan gum, locust bean gum, riboflavin 5 – phosphate sodium, povidone K30, talc and magnesium stearate.

What Prochlorperazine Buccal Tablet look like and contents of the pack

The buccal tablet is yellow colored, circular shaped biconvex uncoated tablet debossed with 'C77' on one side and plain on other side with approximately 5.5 mm in diameter.

Pack size: Blister containing 2, 8, 15, 30, 50, or 60 buccal tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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