

Prochlorperazine maleate (Brown and Burk) 3 mg buccal tablets

What is in this leaflet

Read all of this leaflet carefully before you start taking 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 doctor or pharmacist if you need more information or advice.
 - If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
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What this medicine is used for

Prochlorperazine maleate 3 mg buccal tablets are effective in symptomatic treatment of vertigo (dizziness), treating nausea (feeling sick) and vomiting (being sick), and in the treatment of migraine.

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

Your doctor may have prescribed Prochlorperazine maleate 3 mg buccal tablets for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you use this medicine

What you need to know before you take Prochlorperazine maleate 3 mg buccal tablets

When you must not use it

Do not take this medicine:

- if you are allergic to prochlorperazine maleate or any of the other ingredients of this medicine
- if you are pregnant, or you think you might be pregnant, or breast feeding
- 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
- if you are under 12 years of age

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor:

- if you are elderly
- if you were born with or have a family history of prolonged QT interval, or if you have acquired QT prolongation (seen on ECG, electrical recording of the 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 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.

If you have not told your doctor about any of the above, tell them before you start using this medicine.

Prochlorperazine maleate 3 mg buccal tablets may cause you to be more sensitive to sunlight. When taking the tablets it is particularly important that you should avoid exposure to direct sunlight and use sunscreen.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Prochlorperazine maleate 3 mg buccal tablets.

In particular, tell your doctor or pharmacist if you are taking:

- medicines known to affect the rhythm of your heart. This includes medicines used for abnormal heart rhythm (antiarrhythmics), for depression (tricyclic antidepressants) and for 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).

These medicines may be affected by If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Prochlorperazine maleate 3 mg buccal tablets.

How to take this medicine

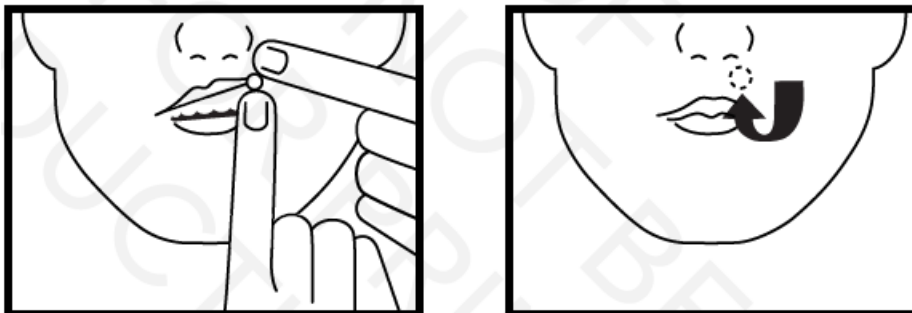
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

This medicine is **not recommended** for children **under 12 years of age**.

INSTRUCTIONS FOR USE

Please read carefully before taking 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 take 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.

When to take it

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

If you forget to take it

If you forget to take a dose do not double the dose next time. Just carry on taking the medicine as the doctor, pharmacist or nurse has told you.

While you are using this medicine

Things you must do

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Prochlorperazine maleate 3 mg buccal tablets.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Do not drink alcohol when taking the tablets as it may interact with this medicine.

Pregnancy and breast feeding

If you are pregnant or thinking of becoming pregnant, you should not take this medicine. Experience with Prochlorperazine maleate 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.

Driving and using machines

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

The tablets contain sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

In case of overdose

If you accidentally take too many tablets **you must** seek medical attention immediately.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine.

Do this even if there are no signs of discomfort or poisoning.

Show any left-over medicine or the empty packet to the doctor.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using this medicine.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Serious side effects

If you experience any of the following side effects, you should **stop taking the 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 and 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 taking medicines of the same type as Prochlorperazine maleate 3 mg buccal tablets compared with those not taking these medicines.

Other side effects include:

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

- jaundice
- blood problems.

Very rare: may affect up to 1 in 10,000 people

- breast swelling (in men as well as in women)
- milk secretion from the breasts 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 itchiness, 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

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using this medicine

Storage

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

Keep the blisters in the outer carton in order to protect from light. Store at or below 25°C.

Do not use after the expiry date (EXP month/year) shown on the outer carton and blister. The expiry date refers to the last day of that month.

Disposal

Return any unused medicine to a pharmacy and any medicine past its expiry date as shown on the dispensing label or on the packaging.

Product description

What it looks like

Yellow, circular shaped biconvex tablet, with 'C77' on one side and plain on other side.

Blister packs of 50 tablets.

Ingredients

Each tablet contains 3 mg of the active ingredient prochlorperazine maleate.

The inactive ingredients are: compressible sugar (sucrose), povidone, xanthan gum, locust bean gum, talc, magnesium stearate and riboflavin sodium phosphate.

Sponsor Details

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