

## **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 use 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.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

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) associated with migraine.

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 this medicine if migraine has previously been diagnosed by your doctor.

#### **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 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 18 years of age

## **Warnings and precautions**

### **Talk to your doctor or pharmacist before using Prochlorperazine tablet**

- if you are elderly
- 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 tablet may cause you to be more sensitive to sunlight. When using Prochlorperazine tablet it is particularly important that you should avoid exposure to direct sunlight and use sunscreen.

### **Other medicines and Prochlorperazine tablet**

Tell your doctor or pharmacist if you are using, have recently taken or might use any other medicines.

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

- 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, drink and alcohol**

Prochlorperazine are best taken after food.

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

### **Pregnancy and breast-feeding**

If you are pregnant or thinking of becoming pregnant, you should not use Prochlorperazine Maleate 3 mg Buccal Tablets.

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

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

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

### **Prochlorperazine tablet contains 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 described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For the treatment of nausea and vomiting in cases of previously diagnosed migraine only, in persons aged 18 years and over: Use 1 or 2 tablets twice a day for a maximum of 2 days.

Prochlorperazine maleate are not recommended for children under 18 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 tablet than you should

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

#### If you forget to use Prochlorperazine tablet

Do not use a double dose to make up for a forgotten. Just carry on using the medicine as the doctor, pharmacist 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.
- 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 maleate compared with those not using these medicines.

**Other side effects include:**

**Unknown: frequency cannot be estimated from the available data**

- drowsiness
- dizziness
- dry mouth
- inability to sleep (insomnia)
- agitation
- 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

**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
- a feeling of restlessness or anxiety that can range from mild to severe.

### **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](http://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 looks 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 or 8 buccal tablets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer**

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This leaflet was last revised in 11/2020