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# **Primege**

PACKAGE LEAFLET: INFORMATION FOR THE USER **PROCHLORPERAZINE MALEATE 3 MG BUCCAL 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 is and what it is used for 2. What you need to know before you take Prochlorperazine 3. How to take Prochlorperazine 4. Possible side effects 5. How to store Prochlorperazine 6. Contents of the pack and other information

# **1. WHAT PROCHLORPERAZINE IS AND WHAT IT IS USED** FOR

The name of your medicine is Prochlorperazine maleate 3 mg Buccal Tablets (referred to as Prochlorperazine throughout this leaflet). Prochlorperazine belongs to a group of medicines called Phenothiazines, which have a variety of effects.

Prochlorperazine is effective in treating nausea (feeling sick) and vomitting (being sick) from what ever cause. They are also used to treat migraine and dizziness due to ear problems and other causes.

# 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PROCHLORPERAZINE

#### Do not take Prochlorperazine if you:

- are allergic (hypersensitive) to prochlorperazine maleate or any of the other ingredients of this medicine (listed in section 6)
- have liver problems
- have blood problems
- suffer from epilepsy, Parkinsons disease or glaucoma
- have problems with your prostate gland

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Prochlorperazine.

If any of the following apply to you, your doctor may decide to alter your treatment.

- Tell you doctor before taking Prochlorperazine if:
- you are elderly
- you are pregnant, thinking of becoming pregnant or breast feeding
- you have risk factors for a blood clot such as high blood pressure, high cholesterol levels, diabetes or you smoke
- someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

# Other medicines and Prochlorperazine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription.

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- Place the tablet high up along your top gum, under the upper lip, on 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 around 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 is best taken **after** meals.

#### If you take more Prochlorperazine than you should

If you think that you, or any other person, may have taken too many tablets, contact your doctor or hospital casualty department immediately. Take any remaining tablets and this leaflet with you so that the medical staff knows exactly what you have taken.

## If you forget to take Prochlorperazine

If you forget to take Prochlorperazine, take it as soon as you remember. Do NOT take a double dose to make up for a forgotten dose.

# **4. POSSIBLE SIDE EFFECTS**

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

# **STOP** taking Prochlorperazine and contact your doctor immediately if you:

- have a high temperature, pale complexion, muscle stiffness and changes in levels of alertness, as you may have developed a serious condition called neuroleptic malignant syndrome.
- 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.

#### Other side effects include:

- drowsiness
- dizziness
- dry mouth
- inability to sleep (insomnia)
- agitation
- mild skin reactions
- low blood pressure (this makes you feel dizzy or faint when you stand up), particularly in the elderly or volume depleted patients (those who have lost both water and salts from the body).

#### Occasional:

• local irritation of the gum and mouth may occur.

#### Rare:

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- jaundice (yellowing of the skin and/or the whites of the eyes)
- blood problems.

# Very rare:

- breast swelling (in men as well as in women)
- abnormal movements, tremors and muscle rigidity, and unusual movements of the face and tongue.

These reactions are unlikely to happen with the low dose of prochlorperazine in this medicine.

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 compared with those not taking these medicines.

# 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: www.mhra.gov. uk/yellowcard

By reporting side effects you can help provide more information on the safety

Tell your doctor or pharmacist if you are taking:

- sedatives or tranquilisers

- medicines used to treat high blood pressure (hypertension). Prochlorperazine may interact with these types of medicines.

#### Prochlorperazine with food and alcohol

Prochlorperazine is best taken after food (see section 3). Do NOT drink alcohol when taking the tablets as it may interact with medicines like Prochlorperazine.

#### Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

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 **NOT** take Prochlorperazine if you are breast-feeding.

## Driving and using machines

Prochlorperazine can cause drowsiness. Do NOT drive or use any tools or machinery when you first start taking this medicine until you know how Prochlorperazine affects you. If in any doubt, speak to your doctor before you drive or use any tools or machinery.

# Prochlorperazine contains sucrose

Prochlorperazine contains sucrose (a sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE PROCHLORPERAZINE**

Always take Prochlorperazine exactly as your doctor 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 over 12 years of age.

#### Use in children

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

#### **INSTRUCTIONS FOR USE**

Please read carefully before taking Prochlorperazine



of this medicine.

# **5. HOW TO STORE PROCHLORPERAZINE**

## 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 and blister. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

# 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Prochlorperazine contains

- The active substance is prochlorperazine maleate. Each tablet contains 3 mg of the active ingredient.
- The other ingredients are: sucrose, locust bean gum, xanthan gum, hypromellose 2910, riboflavin sodium phosphate, magnesium stearate and talc.

# What Prochlorperazine looks like and contents of the pack

Prochlorperazine maleate 3 mg Buccal Tablets are pale yellow, round, biconvex, uncoated and debossed with PC on one side and plain on the other.

The tablets are supplied in blister packs of 30 or 50 tablets.

Not all pack sizes are marketed.

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

Primegen Limited, Unit 15 Moorcroft, Harlington Road, Uxbridge, UB8 3HD, United Kingdom.

# This leaflet was last revised in 08/2015.