



PATIENT INFORMATION LEAFLET

Buccastem[®] 3 mg Buccal Tablets (PROCHLORPERAZINE MALEATE)

INFORMATION FOR THE USER

PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE THIS MEDICINE.

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Buccastem Tablets are and what they are used for
2. Before you take Buccastem Tablets
3. How to take Buccastem Tablets
4. Possible side effects
5. How to store Buccastem Tablets
6. Further Information

1. What is this medicine and what is it used for?

Buccastem 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.

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

2. Before taking Buccastem Tablets

You should only take Buccastem Tablets when your doctor prescribes them for you.

Do not take Buccastem Tablets if you:

- are allergic (hypersensitive) to prochlorperazine maleate or any of the other ingredients
- have problems with your liver
- have blood problems
- suffer from epilepsy, Parkinson's Disease or glaucoma
- have problems with your prostate gland.

You should ask your doctor before taking Buccastem Tablets if you:

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

Taking with other medicines

You should tell your doctor if you are already taking sedatives or tranquilisers, or you are being treated for high blood pressure (hypertension). Buccastem Tablets may interact with these types of medicines.

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

Taking with food and drink

Buccastem Tablets are best taken **after food**.

Do not drink alcohol when taking the tablets as it may interact with medicines like Buccastem.

Pregnancy and breast feeding

If you are pregnant or thinking of becoming pregnant, you should only take Buccastem Tablets on your doctor's instructions.

The following symptoms may occur in newborn babies, of mothers that have used Buccastem 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 Buccastem 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.

Driving and using machines

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

Important information about some of the ingredients of Buccastem Tablets

This product contains sucrose. 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 use Buccastem Tablets

You must follow the instructions that your doctor has given you about how much and when to take Buccastem Tablets.

The usual dosage is one or two tablets twice a day for adults and children over 12 years of age. Buccastem Tablets are **not recommended** for children **under 12 years of age**.

INSTRUCTIONS FOR USE

Please read carefully before taking the tablet.



- 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.

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

If you take more Buccastem Tablets than you should or if you accidentally take too many tablets **you must** seek medical attention immediately.

If you forget to take Buccastem Tablets

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

4. Possible side effects

Like all medicines, Buccastem Tablets can cause side effects, although not everybody gets them. If you have a high temperature, pale complexion, muscle stiffness and changes in levels of alertness, you may have developed a serious condition called neuroleptic malignant syndrome. If you have these symptoms while taking the tablets, **you should immediately inform your doctor.**

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, particularly when you stand up), particularly in elderly or volume depleted patients (those who have lost both water and salts from the body).
- 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.
- 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 Buccastem Tablets compared with those not taking these medicines.

Occasional

- local irritation to the gum and mouth may occur.

Rare

- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store

Keep all medicines out of reach and sight of children.

Keep the blisters in the outer carton in order to protect from light.

This medicinal product does not require any special temperature storage condition.

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.

6. Further information

What Buccastem Tablets contain

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

The other ingredients are: compressible sugar (sucrose), povidone K30, xanthan gum, locust bean gum, talc, magnesium stearate and riboflavin sodium phosphate.

What Buccastem Tablets look like and contents of the pack

The buccal tablet is pale yellow and has JI on one side and is plain on the other.

The product is only available on prescription in packs of 50 tablets.

Marketing Authorisation Holders: Alliance Pharmaceuticals Ltd, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.

PSM Healthcare Ltd trading as API Consumer Brands, PO Box 76 401. Manukau City, Auckland.

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