ALLIANCE

PATIENT INFORMATION LEAFLET

Buccastem® M Tablets

(PROCHLORPERAZINE MALEATE 3 MG,
EQUIVALENT TO 1.85 MG PROCHLORPERAZINE BASE)

PATIENT INFORMATION LEAFLET

**PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU TAKE THIS MEDICINE.
IF YOU ARE NOT SURE ABOUT ANYTHING ASK YOUR PHARMACIST.**

1. WHAT ARE BUCCASTEM M TABLETS?

Buccastem M is a medicine used to treat nausea (feeling sick) and vomiting (being sick) associated with migraine.
Each tablet contains 3 mg of the active ingredient prochlorperazine maleate. The other ingredients are compressible sugar, povidone K30, xanthan gum, locust bean gum, talc, magnesium stearate and riboflavin sodium phosphate.
The product is available from pharmacists in packs of 8 tablets.
The tablet is pale yellow and has JI on one side and is plain on the other.
Marketing Authorisation Holder: Alliance Pharmaceuticals Ltd, Avonbridge House, Bath Road, Chippenham, Wiltshire, SN15 2BB, UK.
Manufacturer: Dales Pharmaceutical Limited, Snaygill Industrial Estate, Keighley Road, Skipton, BD23 2RW, UK.

2. WHAT ARE BUCCASTEM M TABLETS USED FOR?

Prochlorperazine belongs to a large group of drugs known as phenothiazines, which have a variety of effects.
Buccastem M is a product which is effective in treating nausea (feeling sick) and vomiting (being sick) associated with migraine.

3. BEFORE TAKING BUCCASTEM M TABLETS

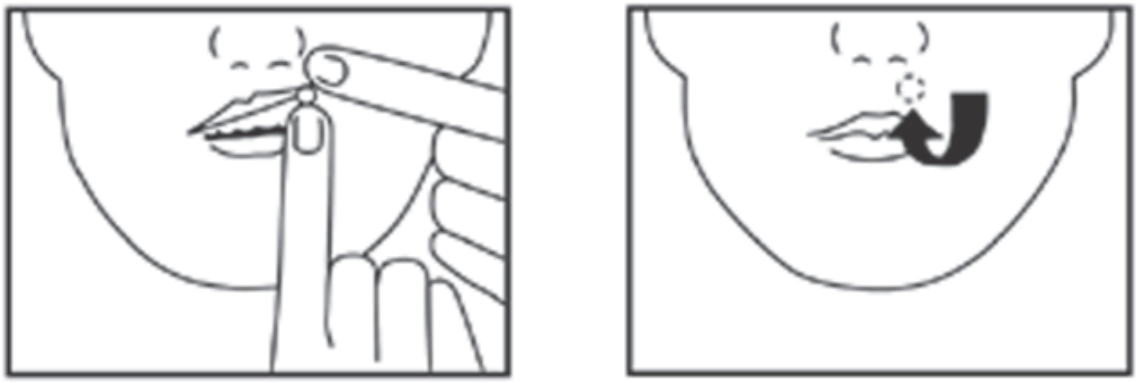
Only use this medicine if migraine has previously been diagnosed by your doctor.
Do not take Buccastem M Tablets if:

- you are allergic to any of the ingredients, or
- you are pregnant, or you think you might be pregnant, or breast feeding, or
- you have problems with your liver, or
- you have blood problems, or
- you have epilepsy or Parkinson's Disease, or
- you have glaucoma, or
- you have problems with your prostate gland, or
- you are under 18 years of age, or
- 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.

Tell your pharmacist if you are taking any other medicines, especially sedatives, tranquillisers, blood thinning medicines, water tablets, propanol or anticonvulsants, or any drug for depression, Parkinson's Disease or high blood pressure.
Alcohol can interact with Buccastem M Tablets.
Do not drive or operate machinery if affected by drowsiness.

4. HOW TO USE BUCCASTEM M TABLETS

INSTRUCTIONS FOR USE
Please read carefully before taking the tablet(s).



Place the tablet high up along the top gum under the upper lip either side of your mouth as indicated above and allow it to dissolve slowly and completely. The tablet will soften and adhere to the gum, taking, for example, between 1 and 2 hours to dissolve completely. 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 more quickly.
If two tablets are required, the second tablet should be placed on the top gum adjacent to the first tablet, but not on top of it. The tablet(s) is best taken after meals. Do not chew or swallow the tablet.
If you wear dentures, the tablet(s) may be placed in any comfortable position between lip and gum.

5. HOW MUCH TO TAKE?

The usual dosage is one or two tablets twice a day for a maximum of 2 days, for adults aged 18 years or over.
If symptoms persist, consult your doctor.
If you forget to take a dose it is not necessary to double the dose next time. Just carry on taking the medicine at the recommended dose.
If you accidently take too many tablets you must seek medical attention at once.

6. WHAT SIDE-EFFECTS MAY OCCUR?

Side-effects that may occur with Buccastem M Tablets are drowsiness, dizziness, dry mouth, inability to sleep (insomnia), agitation, mild skin reactions and low blood pressure, particularly in elderly or dehydrated patients (this makes you feel dizzy or faint, particularly when you stand up). Occasionally, local irritation to the gum and mouth may

occur. Rarely, jaundice (yellowing of the skin and/or the whites of the eyes) and blood problems may occur. Also, rarely, medicines of this type may cause abnormal movements, tremors and muscle rigidity, and usually in young patients an inability to control certain muscles of the body, such as tongue, mouth, arms and legs, or subsequently, breast swelling (in men as well as in women).
These reactions are unlikely to happen with the low dose of prochlorperazine in this medicine. A combination of high temperature, pale complexion, muscle stiffness and changes in levels of alertness are symptoms of a serious condition called neuroleptic malignant syndrome. If you develop these symptoms you should immediately inform your doctor.
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 antipsychotics compared with those not receiving antipsychotics.

Do not drive or operate machinery if affected by drowsiness.
Tell your doctor or pharmacist if you have any undesirable effect after using this product.

7. STORAGE

Keep all medicines safely away from children.
Do not use after expiry date (EXP month/year) shown on the pack.
Protect from light.

Buccastem is a registered trademark of Alliance Pharmaceuticals.

Leaflet last revised October 2010.

XXXXXX

Changes made to PIL

Issue Number	Issue Date	Change	Authority Approval Date	Made By
001	November 2009	Alliance transfer		VS
002		IMB & MHRA surveillance update – VTE (09-240 & 10-003) & elderly 09-240 & 10-004		JR
003		Remove sword & circle		VS
004	June 2010	Remove RB as manufacturer	17/06/2010	VS
005		Typo – ‘povidone’	12/10/10	VS