

DATA SHEET

TRADE NAME OF MEDICINAL PRODUCT

Buccastem 3 mg Buccal Tablets

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each buccal tablet contains 3.0 mg prochlorperazine maleate BP.

PHARMACEUTICAL FORM

Buccal tablet.

CLINICAL PARTICULARS

Therapeutic indications

As a Prescription Medicine:

Symptomatic treatment of vertigo due to Meniere's Disease, Labyrinthitis and other causes.
For nausea and vomiting from whatever cause.
In the treatment of migraine.

As a Pharmacist Only Medicine:

In the treatment of nausea associated with migraine.

The sale of up to 10 tablets by pharmacists for the treatment of nausea associated with migraine or, when sold by nurses or pharmacists accredited to sell the emergency contraceptive pill, for the prevention of nausea associated with emergency contraception.

Posology and method of administration

To be placed in the buccal cavity.

Adults and children aged 12 years and over: One or two Buccastem 3 mg Buccal Tablets twice a day.

Children under 12 years: Not recommended.

Elderly patients: There is no evidence that dosage need be modified for the elderly.

Contraindications

Buccastem 3 mg Buccal Tablets is contraindicated in patients with impaired liver function, existing blood dyscrasias, epilepsy, Parkinson's Disease, prostatic hypertrophy, narrow angle glaucoma and known hypersensitivity to the active ingredient.

Special warnings and special precautions for use

Hypotension, usually postural, may occur, particularly in elderly or volume depleted patients. Tardive dyskinesia may occur occasionally, although this is normally associated with higher doses than are recommended for Buccastem 3 mg Buccal Tablets. Nausea and vomiting as a sign of organic disease may be masked by the anti-emetic action of Buccastem 3 mg Buccal Tablets.

Cases of venous thromboembolism (VTE) have been reported with antipsychotic drugs. Since patients treated with antipsychotics often present with acquired risk factors for VTE, all

possible risk factors for VTE should be identified before and during treatment with Buccastem 3 mg Buccal Tablets and preventive measures undertaken.

Increased Mortality in Elderly People with Dementia

Data from two large observational studies showed that elderly people with dementia who are treated with antipsychotics are at a small increased risk of death compared with those who are not treated. There are insufficient data to give a firm estimate of the precise magnitude of the risk and the cause of the increased risk is not known.

Buccastem 3mg Buccal Tablets is not licensed for the treatment of dementia-related behavioural disturbances.

Interaction with other medicaments and other forms of interaction

Alcohol and CNS depressants should be used with caution as should α -adrenoreceptor blocking antihypertensives.

Pregnancy and lactation

There is inadequate evidence of the safety in human pregnancy, although prochlorperazine has been used for many years without apparent ill-effect. However, Buccastem 3 mg Buccal Tablets/ prochlorperazine maleate should be avoided unless absolutely necessary during the first trimester of pregnancy. Since data from animal studies show that prochlorperazine may be found in breast milk, Buccastem 3 mg Buccal Tablets should not be used during lactation.

Neonates exposed to antipsychotics (including prochlorperazine) during the third trimester of pregnancy are at risk of adverse reactions including Extrapyramidal and/or withdrawal symptoms that may vary in severity and duration following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress, or feeding disorder. Consequently, newborns should be monitored carefully.

Effect on ability to drive and use machines

Patients who drive or operate machinery should be warned of the possibility of drowsiness.

Undesirable effects

Drowsiness, dizziness, dry mouth, insomnia, agitation and mild skin reactions may occur. Extrapyramidal reactions are very unlikely at the recommended dosage. Other effects which have occurred rarely with prochlorperazine and other phenothiazine neuroleptics include jaundice, blood dyscrasias and, very rarely, hyperprolactinaemic effects such as gynaecomastia. Neuroleptic malignant syndrome (hyperthermia, rigidity, autonomic dysfunction and altered consciousness) may occur with any neuroleptic. Use of Buccastem 3 mg Buccal Tablets may occasionally result in local irritation to the gum and mouth.

Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs - frequency unknown.

System Organ Class: Pregnancy, puerperium and perinatal conditions.

Adverse Drug Reaction/Frequency: Drug withdrawal syndrome neonatal (see ***Pregnancy and Lactation*** Section/ Not known.

Overdose

The signs and symptoms will be predominantly extrapyramidal and may be accompanied either by restlessness and agitation or central nervous depression. Hypotension may also occur. Treatment is essentially symptomatic and supportive. There is no specific antidote. Gastric lavage is helpful, particularly when carried out within 6 hours of ingestion. Do not

induce vomiting. Particular attention must be directed to maintaining a clear airway since this may be threatened by extrapyramidal muscle dystonias. Severe dystonic reactions usually respond to procyclidine (5-10 mg) or orphenadrine (20-40 mg) given i.m. or i.v. If convulsions occur they should be treated using i.v. diazepam. If hypotension is present, strict attention to ventilation and posturing of the patient will often secure the desired effect, but failing this, consideration should be given to volume expansion by i.v. fluids. If this is insufficient, positive inotropic agents such as dopamine may be tried, but peripheral vasoconstrictor agents are not generally recommended. Adrenaline should NOT be used.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Prochlorperazine is a member of the phenothiazine group of neuroleptics which, in doses lower than those used in psychiatry, is usually employed for its anti-emetic properties. The site of action is thought to be the chemoreceptor trigger zone.

Pharmacokinetic properties

Buccastem 3 mg Buccal Tablets are placed in the buccal cavity where they form a gel from which the prochlorperazine is released and absorbed. The plasma levels achieved at steady-state on a dosage regimen of one Buccastem 3 mg Buccal Tablet twice daily are similar to those observed with the standard oral dosage of one 5 mg tablet taken three times daily. The elimination half-life of prochlorperazine in this formulation is 9.0 hours, similar to that observed with the oral formulation.

Preclinical safety data

No preclinical findings of relevance have been reported.

PHARMACEUTICAL PARTICULARS

List of excipients

Compressible sugar, povidone K30, xanthan gum, locust bean gum, talc, magnesium stearate and riboflavin sodium phosphate.

Incompatibilities

None.

Shelf-life

Three years for blister packs.

Special precautions for storage

Protect from light.

Nature and contents of container

250 micron PVC aluminium foil blister.

Pack size

Blister packs of 50 tablets (Prescription Medicine)

Instructions for use/handling

To be placed in the buccal cavity.

MEDICINES CLASSIFICATION

1. Prescription Medicine (50 tablet blister pack)
2. Pharmacist Only Medicine (The sale of up to 10 tablets by pharmacists for the treatment of nausea associated with migraine or, when sold by nurses or pharmacists accredited to sell the emergency contraceptive pill, for the prevention of nausea associated with emergency contraception.)

NAME AND ADDRESS

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