

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Prochlorperazine maleate 3mg Buccal Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each buccal tablet contains prochlorperazine maleate 3mg.
Each tablet also contains 53.090mg of sucrose.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Buccal tablet.
Pale yellow, round, biconvex, uncoated tablet debossed with PC on one side and plain on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over: One or two tablets twice a day.

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

Paediatric population

Children under 12 years: Not recommended.

Method of administration

To be placed in the buccal cavity, high up along the top gum under the upper lip, until dissolved. Do not chew or swallow the tablet.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

Contraindicated in patients with impaired liver function, existing blood dyscrasias, epilepsy, Parkinsons Disease, prostatic hypertrophy, narrow angle glaucoma and known hypersensitivity to the active ingredient or any of the ingredients of this product.

4.4 Special warnings and 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 prochlorperazine buccal tablets. Nausea and vomiting as a sign of organic disease may be masked by the anti-emetic action of prochlorperazine 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 Prochlorperazine buccal tablets and preventative 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.

Prochlorperazine buccal tablets are not licensed for the treatment of dementia-related behavioural disturbances.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Pregnancy

There is inadequate evidence of the safety in human pregnancy, although prochlorperazine has been used for many years without apparent ill-effect. However, prochlorperazine buccal tablets should be avoided unless absolutely necessary during the first trimester of pregnancy.

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.

Breast-feeding

Animal studies show that prochlorperazine may be found in breast milk, hence it should not be used during lactation.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The following adverse reactions are classified by system organ class and ranked under heading of frequency using the following convention:

System Organ Class	Frequency	Adverse Reactions
Blood and lymphatic system disorders	Not known	Blood dyscrasias
Endocrine disorders	Not known	hyperprolactinaemic effects such as gynaecomastia
Psychiatric disorders	Not known	Insomnia, agitation

Nervous system disorders	Not known	Dizziness, Drowsiness, Extrapyrarnidal reactions, Neuroleptic malignant syndrome (hyperthermia, rigidity, autonomic dysfunction and altered consciousness) may occur with any neuroleptic
Vascular disorders	Not known	Thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs
Gastrointestinal disorders	Not known	dry mouth, local irritation to the gum and mouth
Hepatobiliary disorders	Not known	neuroleptics include jaundice
Skin and subcutaneous tissue disorders	Not known	mild skin reactions
Pregnancy, puerperium and perinatal conditions	Not known	Pregnancy, puerperium and perinatal conditions
General disorders and administration site conditions	Not known	Drug withdrawal syndrome neonatal (see section 4.6)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms

The signs and symptoms will be predominately extrapyramidal and may be accompanied either by restlessness and agitation or central nervous depression. Hypotension may also occur.

Management

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 (5-10mg) or orphenadrine (20-40mg) 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Phenothiazines with piperazine structure, ATC code: N05AB04

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.

5.2 Pharmacokinetic properties

Absorption

Prochlorperazine 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 3mg buccal tablet twice daily are similar to those observed with the standard oral dosage of one 5mg tablet taken three times daily.

Elimination

The elimination half-life of prochlorperazine in this formulation is 9.0 hours, similar to that observed with the oral formulation.

5.3 Preclinical safety data

No preclinical findings of relevance have been reported

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Locust bean gum
Xanthan gum

Hypromellose 2910
Riboflavin sodium phosphate
Magnesium stearate
Talc

6.2 Incompatibilities

None known

6.3 Shelf life

30 Months

6.4 Special precautions for storage

No special storage conditions required.

6.5 Nature and contents of container

Tablets are packed in PVC/PVDC or OPA/Al/PV//Al blister packs containing 30 or 50 tablets. Not all packs are marketed.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Focus Pharmaceuticals Ltd
Dashwood House,
69 Old Broad Street,
London, EC2M 1QS,

United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 20046/0308

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

17/01/2025

10 DATE OF REVISION OF THE TEXT

17/01/2025