SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Prochlorperazine maleate 3 mg Buccal Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each buccal tablet contains 3.0 mg prochlorperazine maleate

Excipient with known effect: Compressible sugar (contains sucrose) 52.490 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Buccal tablet.

Yellow colored, circular shaped biconvex uncoated tablet debossed with ‘C77’ on one side and plain on other side with approximately 5.5 mm in diameter.

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

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.

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

Children under 12 years: Not recommended.

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

4.3 Contraindications

• Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
• Impaired liver function
• Existing blood dyscrasias
• Epilepsy
• Parkinsons Disease
• Prostatic hypertrophy
• Narrow angle glaucoma

4.4 Special warnings and precautions for use

Prochlorperazine 3 mg Buccal Tablets should be avoided in patients with stroke risk factors and myasthenia gravis.

Agranulocytosis has been reported with phenothiazines. The occurrence of unexplained infections or fever may be evidence of blood dyscrasia (see section 4.8), and requires immediate haematological investigation.

It has been reported that patients with AIDS may be particularly susceptible to antipsychotic-induced extrapyramidal effects.

Because of the risk of photosensitisation, patients should be advised to avoid exposure to direct sunlight and use sunscreen (see section 4.8).

Hypotension, usually postural, may occur, particularly in elderly or volume depleted patients.

Nausea and vomiting as a sign of organic disease may be masked by the anti-emetic action.

Neuroleptic malignant syndrome (NMS) is a potentially fatal symptom complex associated with antipsychotic medicinal products. Alteration in mental status and other neurological signs often precede systemic signs of NMS. It is imperative that treatment be discontinued in the event of NMS (characterised by unexplained fever, hyperthermia, autonomic dysfunction, altered consciousness, muscle rigidity) (see section 4.8).

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, and preventive measures undertaken (see section 4.8).

QT prolongation

Neuroleptic phenothiazines may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal. Prochlorperazine 3 mg Buccal Tablets should be used with caution in patients with congenital or documented acquired QT prolongation and/or known risk factors for prolongation of the QT interval such as:

- cardiac disease e.g. heart failure, myocardial infarction
- proarrhythmic conditions e.g bradycardia (< 50 bpm)
- a history of ventricular dysrhythmias
- uncorrected hypokalemia and/or hypomagnesemia
- and during concomitant administration with QT interval prolonging drugs (see section 4.5).

If signs of cardiac arrhythmia occur during treatment with Prochlorperazine 3 mg Buccal Tablets, treatment should be stopped and an ECG should be performed.

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

The tablet contains sucrose

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

4.5 Interaction with other medicinal products and other forms of interaction

Alcohol and CNS depressants should be used with caution due to the possible additive CNS depressant effect.

The hypotensive effect of antihypertensive drugs may be exaggerated.

The mild anticholinergic effect of neuroleptics may be enhanced by other anticholinergic drugs.

Oral anticoagulants – may have diminished effect.

Anticonvulsants – efficacy may be diminished necessitating dosage adjustment, as prochlorperazine may lower the seizure threshold.

The concomitant use of lithium may result in severe extrapyramidal side effects or severe neurotoxicity.

The concurrent use of desferrioxamine and prochlorperazine should be avoided.

Prochlorperazine opposes the effects of levodopa.

There is an increased risk of arrhythmias when neuroleptics are used with concomitant QT prolonging drugs (including certain anti-arrhythmics, antidepressants, macrolide antibiotics and other antipsychotics) and drugs causing electrolyte imbalance (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy
There is inadequate evidence of the safety in human pregnancy. There is evidence of harmful effects in animals. Prochlorperazine Maleate 3 mg Buccal Tablets should be avoided pregnancy unless the physician considers it essential. Neuroleptics may occasionally prolong labour and at such time should be withheld until the cervix is dilated 3-4 cm. Possible adverse effects on the neonate include lethargy or paradoxical hyperexcitability, tremor and low apgar score.

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
Since data from animal studies shows that prochlorperazine may be found in breast milk, Prochlorperazine Maleate 3 mg Buccal Tablets should not be used during breastfeeding.

Fertility
There are no data from on the effects of prochlorperazine on fertility.

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

Undesirable effects are listed by MedDRA System Organ Classes. Assessment of undesirable effects is based on the following frequency groupings:
Very common: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: cannot be estimated from the available data

Tabulated list of adverse reactions

System organ class	**Undesirable effect and frequency**
Blood and lymphatic system disorders	*Rare:* Blood dyscrasia
Immune system disorders	*Not known:* Hypersensitivity reactions such as rash and angioedema
Endocrine disorders	*Very rare*: Hyperprolactinaemia which may result in gynaecomastia, galactorrhoea and amenorrhoea
Metabolism and nutrition disorders	*Not known:* Hyponatraemia Syndrome of inappropriate antidiuretic hormone secretion Hyperglycaemia Glucose tolerance impaired
Psychiatric disorders	*Not known:* Insomnia Agitation
Nervous system disorders	*Not known:* Convulsion Drowsiness Dizziness Extrapyramidal reactions including acute dystonia, akathisia, parkinsonism and tardive dyskinesia
Cardiac disorders	*Not Known;* Arrythmia* QT Prolongation*
Vascular disorders	*Not known:* Hypotension (usually orthostatic)
Gastrointestinal disorders	*Not known*: Dry mouth Irritation gum Mouth irritation Hypoaesthesia oral Paraesthesia oral Taste disorders
Hepatobiliary disorders	*Rare*:

	Jaundice *Not known:* Cholestasis
Skin and subcutaneous tissue disorders	*Not known:* Skin reaction Photosensitivity (see section 4.4)
Pregnancy, puerperium and perinatal conditions	*Not known:* Drug withdrawal syndrome neonatal (see Section 4.6)

* See 'Description of selected adverse reactions'

Description of selected adverse reactions

Impotence, ejaculation disorder, priapism, and agranulocytosis (see section 4.4) are class effects associated with phenothiazines.

Neuroleptic malignant syndrome may occur with any neuroleptic (see section 4.4).

Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs- Frequency unknown (see section 4.4).

QT prolongation, cardiac arrhythmias, including ventricular arrhythmias which may result in ventricular fibrillation or cardiac arrest have been reported during neuroleptic phenothiazine therapy. Pre-existing cardiac disease, proarrhythmic conditions, hypokalaemia, hypomagnesemia, or concomitant administration with QT interval prolonging drugs may predispose.

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

4.9 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. 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 or orphenadrine 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

The 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 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.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Compressible sugar
Povidone
Xanthan gum
Locust bean gum
Riboflavin 5-phosphate sodium
Talc
Magnesium stearate

6.2 Incompatibilities

None.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVdC aluminium foil blisters.

Pack size:

Blister packs of 2, 8, 15, 30, 50, or 60 buccal tablets

Not all pack sizes may be marketed

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. Marketing authorisation holder

Brown & Burk UK Ltd
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Middlesex
TW4 5DQ
United Kingdom.

8. Marketing authorisation number(s)

PL 25298/0150

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

26/03/2025

10. DATE OF REVISION OF THE TEXT

26/03/2025