# 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 mg prochlorperazine maleate.

It also contains 48.09 mg sucrose.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Buccal Tablet.

Pale yellow to yellow, circular, biconvex uncoated tablets debossed with “P3” on one side and plain on the other side.

### 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 Prochlorperazine maleate 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.

### 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
- Parkinson's Disease
- Prostatic hypertrophy
- Narrow angle glaucoma

## 4.4 Special warnings and precautions for use

Prochlorperazine maleate 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 of prochlorperazine maleate 3 mg buccal tablets.

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 with prochlorperazine maleate 3 mg buccal tablets and preventive measures undertaken (see section 4.8).

**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 maleate 3 mg buccal tablet is not licensed for the treatment of dementia-related behavioural disturbances.

**Prochlorperazine maleate 3 mg buccal tablets contain sucrose**

Prochlorperazine maleate 3 mg buccal tablets contain sucrose. Hyperglycaemia or intolerance to glucose has been reported in patients treated with antipsychotic phenothiazines. Patients with an established diagnosis of

diabetes mellitus or with risk factors for the development of diabetes, who are started on Prochlorperazine, should get appropriate glycaemic monitoring during treatment (see section 4.8).

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

**.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 hypotensive effect of antihypertensive drugs may be exaggerated.

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 maleate 3 mg buccal tablets oppose the effects of levodopa.

## 4.6 Fertility, pregnancy and lactation

There is inadequate evidence of the safety in human pregnancy.
Prochlorperazine maleate 3 mg buccal tablets 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, it 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.

## 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 effects and frequency** |
|---|---|
| Blood and lymphatic system disorders | *Rare:*<br>Blood dyscrasia |
| Immune system disorders | *Not known:*<br>Hypersensitivity reactions such as rash and angioedema |
| Endocrine disorders | *Very rare:*<br>Hyperprolactinaemia which may result in gynaecomastia, galactorrhoea and amenorrhoea |
| Metabolism and nutrition disorders | *Not known:*<br>Hyponatraemia<br>Syndrome of inappropriate antidiuretic hormone secretion<br>Hyperglycaemia<br>Glucose tolerance impaired |
| Psychiatric disorders | *Not known:*<br>Insomnia<br>Agitation |
| Nervous system disorders | *Not known:*<br>Convulsion<br>Drowsiness<br>Dizziness<br>Extrapyramidal reactions including acute dystonia, akathisia, parkinsonism and tardive dyskinesia |
| Vascular disorders | *Not known:*<br>Hypotension (usually orthostatic) |

| | |
|---|---|
| Gastrointestinal disorders | *Not known:*<br>Dry mouth<br>Irritation gum<br>Mouth irritation<br>Hypoaesthesia oral<br>Paraesthesia oral<br>Taste disorders |
| Hepatobiliary disorders | *Rare:*<br>Jaundice<br>*Not known:*<br>Cholestasis |
| Skin and subcutaneous tissue disorders | *Not Known:*<br>Skin reaction<br>Photosensitivity (see section 4.4) |
| Pregnancy, puerperium and perinatal conditions | *Not known:*<br>Drug withdrawal syndrome neonatal (see Section 4.6) |

**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).

**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

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: Antipsychotics, 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

Prochlorperazine maleate 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 prochlorperazine maleate 3 mg buccal tablets 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

No preclinical findings of relevance have been reported

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Sucrose

Povidone (K-30)

Riboflavin Sodium Phosphate

Xanthan Gum (FF)

Talc

Magnesium Stearate

### 6.2 Incompatibilities

None

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Store below 25°C in original package.

### 6.5 Nature and contents of container

Tablets are packed in Alu/PVC/PVdC blisters

Pack Size: 14,30, 50 and 60 tablets.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

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

## 7 MARKETING AUTHORISATION HOLDER

Key Pharmaceuticals Ltd.

Galen House, 83 High Street,

Somersham, Cambridgeshire,

PE28 3JB, UK

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 34424/0032

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

13/05/2025

## 10 DATE OF REVISION OF THE TEXT

15/02/2022