For the Use of a Registered Medical Practitioner

1. GENERIC NAME AND BRAND NAME

Prochlorperazine Buccal Tablets BP 3mg
Stemetil® VM

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated buccal tablet contains:
Prochlorperazine Maleate I.P. 3mg
Excipients q.s.

3. DOSAGE FORM AND STRENGTH

Refer Section 1 & 2

4. CLINICAL PARTICULARS

4.1. THERAPEUTIC INDICATIONS

For treatment of nausea, vomiting, post operative emesis & migraines.

4.2. POSOLOGY AND METHOD OF ADMINISTRATION

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

Hypersensitivity to the active substance or to any of the excipients listed.

- Impaired liver function
- Existing blood dyscrasias
- Epilepsy
- Parkinson's Disease
- Prostatic hypertrophy
- Narrow angle glaucoma
- SIDS

4.4. SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Prochlorperazine Buccal Tablets BP 3mg 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 and requires immediate hematological investigation.
It has been reported that patients with AIDS may be particularly susceptible to antipsychotic-induced extrapyramidal effects.
Because of the risk of photosensitization, patients should be advised to avoid exposure to direct sunlight and use sunscreen.
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 (characterized by unexplained fever, hyperthermia, autonomic dysfunction, altered consciousness, muscle rigidity)
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.

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 Buccal Tablets BP 3mg 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

If signs of cardiac arrhythmia occur during treatment with Prochlorperazine Buccal Tablets BP 3mg, 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 Buccal Tablets BP 3mg is not licensed for the treatment of dementia-related behavioral disturbances.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency should not take this medicine.

Signs of infection, use in depression, stroke, alcohol use, and use in elderly patients.

4.5. DRUG INTERACTIONS

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.
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 deferoxamine and prochlorperazine should be avoided.
There is an increased risk of arrhythmias when neuroleptics are used with concomitant QT prolonging drugs (including certain anti-arrhythmic, antidepressants, macrolide antibiotics and other antipsychotics) and drugs causing electrolyte imbalance.

4.6. USE IN SPECIAL POPULATION

There is inadequate evidence of the safety in human pregnancy. Prochlorperazine Buccal Tablets BP 3mg is contraindicated during 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.

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:* Hyperprolactinemia which may result in gynecomastia, galactorrhea, and amenorrhea
Metabolism and nutrition disorders	*Not known:* Hyponatremia Syndrome of inappropriate antidiuretic hormone secretion Hyperglycemia 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. Hypoesthesia oral Paresthesia oral Taste disorders
Hepatobiliary disorders	*Rare:* Jaundice *Not known:* Cholestasis
Skin and subcutaneous tissue disorders	*Not known:* Skin reaction Photosensitivity
Pregnancy, puerperium, and perinatal conditions	*Not known:* Drug withdrawal syndrome neonatal

Description of selected adverse reactions
Impotence, ejaculation disorder, priapism, and agranulocytosis are class effects associated with phenothiazines.

Neuroleptic malignant syndrome may occur with any neuroleptic.

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

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, hypokalemia, hypomagnesemia, or concomitant administration with QT interval prolonging drugs may predispose.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

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 IM or IV If convulsions occur, they should be treated using IV 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 IV 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 PROPOERTIES

5.1. MECHANISM OF ACTION

At therapeutic doses, prochlorperazine is mainly dopamine antagonist but it also has anticholinergic and anti-adrenoceptor blocking activity. Its actions on dopamine receptors in the medulla chemoreceptor trigger zone probably accounts for its anti-emetic effects. Unwanted effects results from the drugs dopamine and adrenoceptor antagonism. Dystonias and dyskinesias and parkinsonism in the elderly can occur with prolonged use or high dosage. Postural hypotension and excessive sedation are risks, especially in the elderly.

Prochlorperazine is a propyl piperazine derivative of phenothiazine. Like other phenothiazines, it exerts an antiemetic effect through a depressant action on the chemoreceptor trigger zone. It also has a clinically useful antipsychotic effect.

5.2. PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Phenothiazines with piperazine structure

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.

5.3. PHARMACOKINETICS 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.

6. NON-CLINICAL PROPERTIES

6.1. ANIMAL TOXICOLOGY AND PHARMACOLOGY

No preclinical findings of relevance have been reported.

7. DESCRIPTION

White to off white circular, flat tablets, plain on both sides.

8. PHARMACEUTICAL PARTICULARS

8.1. INCOMPATIBILITIES
None

8.2. SHELF-LIFE
Refer pack.

8.3. PACKAGING INFORMATION
Refer pack.

8.4. STORAGE AND HANDLING INSTRUCTIONS
Refer pack.

9. PATIENT COUNSELLING INFORMATION
You should only take Prochlorperazine Buccal Tablets when your doctor prescribes them for you.
Do not take Prochlorperazine Buccal Tablets:

- if you are allergic to prochlorperazine maleate
- if you have problems with your liver
- if you have blood problems
- if you suffer from epilepsy, Parkinson's Disease, or glaucoma.
- if you have problems with your prostate gland.

Talk to your doctor before taking Prochlorperazine Buccal Tablets:

- if you are elderly
- if you were born with or have a family history of prolonged QT interval, or if you have acquired QT prolongation (seen on ECG, electrical recording of the heart)
- if you have heart disorders or have a history of heart attack (myocardial infarction)
- if you have salt imbalance in the blood (especially low level of potassium or magnesium) • if you are pregnant, thinking of becoming pregnant or breast feeding.
- if you have risk factors for a blood clot or stroke such as high blood pressure, high cholesterol levels, diabetes, or smoking.
- if 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.
- if you have a condition called myasthenia gravis, which causes muscle weakness.
- if you have AIDS

Prochlorperazine Buccal Tablets with food and drink Prochlorperazine Buccal Tablets are best taken after food. Do not drink alcohol when taking the tablets as it may interact with medicines like Prochlorperazine. Pregnancy and breast feeding If you are pregnant or thinking of becoming pregnant, you should only take Prochlorperazine Buccal Tablets on your doctor's instructions.

Driving and using machines
Prochlorperazine Buccal Tablets can make you feel drowsy. Therefore, you should avoid driving or using dangerous machines until you know how the tablets affect you. Prochlorperazine Buccal Tablets

contain sucrose If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The recommended dose is one or two tablets twice a day for adults and children over 12 years of age. Prochlorperazine Buccal Tablets are not recommended for children under 12 years of age.

Place the tablet high up along your top gum, under the upper lip either side of your mouth as indicated above.
The tablet must not be swallowed whole or chewed.
The tablet will soften and adhere to the gum. Allow it to dissolve slowly and completely - this may take between 1 and 2 hours. 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 too quickly.
If you wear dentures, the tablet may be placed in any comfortable position between your lip and gum.
The tablet(s) is best taken after meals. **If you take more Prochlorperazine Buccal Tablets than you should:** If you accidentally take too many tablets you must seek medical attention immediately. Show any left-over medicines or the empty packet to the doctor. **If you forget to take Prochlorperazine Buccal Tablets**: If you forget to take a dose do not double the dose next time. Just carry on taking the medicine as the doctor has told you.

10. DETAILS OF MANUFACTURER

Refer Pack for manufacturer details.

MARKETED BY:
Abbott Healthcare Pvt. Ltd.
Angel Space, Bldg. D-4, Gala No. 1 to 3 & 11 to 13 Ground Floor,
101 to 106 & 111 to 116 First Floor, 201 to 206 & 211 to 216
2nd Floor, Pimplas, Dist. Thane, Bhiwandi-421 302, Maharashtra, India.

11. DETAILS OF LICENSE NO. WITH DATE

31/UA/2013 dated 07-Feb-2025

12. DATE OF REVISION

Version 1.0 dated 12-Mar-25

For product complaints and queries please write to
webmasterindia@abbott.com

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