Summary Product Characteristics

1. **Name of the proprietary product: BLEORMINE**

   Name of the nonproprietary International Product: Promethazine Teoclate Tablets BP 25 mg

   Route of Administration: Oral

2. **Qualitative and Quantitative composition:**

No	Ingredients	Specifi-cation	Quantity /Tablet (mg)	% overages	Reason for inclusion
DRY MIXING					
1.	Promethazine Teoclate	BP	26.25	Nil	Active
2.	Maize starch	BP	110.50	Nil	Binder
3.	Dibasic Calcium Phosphate	BP	45.00	Nil	Diluent
4.	Microcrystalline Cellulose	BP	43.00	Nil	Diluent
BINDER PREPARATION					
5.	Maize starch	BP	5.00	Nil	Binder
6	Povidone K 30	BP	2.25	Nil	Binder
7.	Purified Water	BP	q.s.	Nil	Solvent
LUBRICATION					
8.	Sodium Starch Glycolate	BP	2.00	Nil	Disintegrant
9.	Magnesium stearate	BP	2.00	Nil	Lubricant
10.	Purified Talc	BP	4.00	Nil	Diluent
11.	Colloidal anhydrous silica	BP	5.00	Nil	Glidant

BP: British Pharmacopoeia, q.s.: quantity sufficient

3. Pharmaceutical Form: Tablets

4. Clinical Particulars:

4.1 Therapeutic Indications:
Promethazine Teoclate is a long acting anti –emetic, indicated for
-Prevention and treatment of nausea and vomiting, including motion sickness and post operative vomiting.
-Vertigo due to Menieres syndrome, labyrinthitis and causes.

4.2 Posology and method of administration:
Adults - Travel sickness
Prevention
Long journeys: 1 tablet each night at bedtime commencing on the night before travelling.
Short journeys: 1 tablet to be taken 1 to 2 hours before the journey commences.
Treatment: 1 tablet followed by a second tablet the same evening and a third tablet on the following evening. Prompt treatment is important. Additional tablets may safely be taken as a preventive or when they appear to be needed but it will seldom be necessary to give more than 4 tablets in 24 hours or to repeat a dose in less than 8 hours.

4.3 Contraindications
BLEORMINE should not be used in patients who are in a coma or suffering from CNS depression of any cause. It must not be given to patients hypersensitive to promethazine, phenothiazines or to any of the excipients. BLEORMINE should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days. Use in children: BLEORMINE should not be used in children less than ten years of age.

4.4 Special warnings and precautions for use
Care is necessary with patients who take alcohol, anticholinergic agents, tricyclic antidepressants, sedatives or hypnotics, as such agents are enhanced by BLEORMINE. It may cause mild and temporary confusion or disorientation in certain individuals. It should, therefore, be used with caution in persons in charge of vehicles until their reaction to the drug is known.
BLEORMINE may thicken or dry lung secretions and impair expectoration, it should therefore be used with caution in patients with asthma, bronchitis or bronchiectesis. Use with care in patients with severe coronary artery disease, narrow angle glaucoma, epilepsy or hepatic and renal insufficiency. Caution should be exercised in patients with bladder neck or pyloroduodenal obstruction. Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs; e.g. salicylates.
It may also delay the early diagnosis of intestinal obstruction or raised intracranial pressure through the suppression of vomiting.
BLEORMINE may interfere with immunologic urine pregnancy tests to produce false-positive or false-negative results. BLEORMINE should be discontinued at least 72 hours before the start of skin tests using allergen extracts as it may inhibit the cutaneous histamine response thus producing false-negative results.
In nausea and vomiting of unknown origin, it is essential to establish the diagnosis before giving an antiemetic, to ensure that a serious underlying condition is not masked.

There have been case reports of drug abuse with promethazine. The risk of abuse is greater in patients with a history of drug abuse, As with neuroleptics, Neuroleptic Malignant Syndrome (NMS) characterised by hyperthermia, extrapyramidal disorders, muscle rigidity, altered mental status, autonomic nervous instability and elevated CPK, may occur. As this syndrome is potentially fatal, promethazine must be discontinued immediately and intensive clinical monitoring and symptomatic treatment should be initiated.

4.5 Interaction with other medicinal products and other forms of interaction:
Promethazine Teoclate may enhance the action of any anticholinergic agent,tricyclic antidepressant ,sedative or hypnotic.Alcohol should be avoided during treatment.]

Promethazine Teoclate may interfere with immunologic urine pregnanacy tests to produce false – positive and false –negative result.

Promethazine Teoclate should be discontinued at least 72 hours before any skin tests using extracts as it may inhibit the cutaneous histamine response thus producing false- negative results.

4.6 Pregnancy and Lactation:
Pregnancy
It should not be used in pregnancy unless the physician considers it essential.The use of Promethazine Teoclate tablets is not recommended in the two prior to delivery in view of the risk of irritability and excitement in the neonate.

Lactation
Availability evidence suggests that the amount excreted in milk is insignificant.However, there are risks of neonets irritability and excitements.

4.7 Effects on the ability to drive and use machines
Ambulant patients receiving Promethazine Teoclate for the first time should not be in control of vehicles or machinery for the first few days until it is established that they are not hypersensitive to the central nervous effects of the drug and do not suffer from disorientation,confusion or dizziness.

4.8 Undesirable effects:
More common reactions
Gastrointestinal. Dry mouth, epigastric distress, loss of appetite, nausea, vomiting, diarrhoea, constipation.
Nervous system. Sedation, restlessness, dizziness, lassitude, incoordination, fatigue. Ocular. Blurred vision.
Less common reactions
Cardiovascular. Tachycardia, bradycardia, faintness, palpitations, hypotension, arrhythmias.
Dermatological. Contact dermatitis (topical), photosensitisation, urticaria, angioneurotic oedema.
Haematological. Leucopenia, agranulocytosis, aplastic anaemia, thrombocytopenic purpura.
Hepatic. Jaundice. Musculoskeletal. Extrapyramidal symptoms.

Nervous system. Tinnitus, euphoria, nervousness, insomnia, convulsive seizures, oculogyric crises, excitation, catatonic-like states, hysteria, extrapyramidal symptoms, tardive dyskinesia, Neuroleptic Malignant Syndrome.
Respiratory. Marked irregular respiration.
Immunological. Very rare cases of allergic reactions, including urticaria, rash, pruritus, and anaphylaxis have been reported.
Other. Headaches, nightmares, urinary retention.

Serious or life-threatening reactions
Agranulocytosis. Care is needed in the intramuscular administration of promethazine to children. A severe neurological reaction resulting in coma is possible.

4.9 Overdose
Common features may include nausea,vomiting ,flushing,dilated pupils,dry mouth and tongue,hot dry skin,fever,drowsiness and delirium.Symptoms of severe overdosage are variable.They are characterized in children by various combinations of excitement,ataxia,inco- ordination ,athetosis and hallucinations,while adults may become drowsy and lapse into coma.
Convulsions may occur in both adults and children; coma or excitement may precede their occurance. Cardiac conduction abnormalities and dysrhythmias may occur, cardiorespiratory depression is uncommon. Patients who have been unconscious may be hypothermic.

5. Pharmacological Particulars:

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Histamine H_1 receptor antagonist; antihistamine

ATC code: R06AD02

Mechanism of action:
Promethazine Teoclate is a long acting antihistamine with anti-emetic, central sedative and anticholinergic properties.
Promethazine is metabolized in the liver (the major metabolite being the sulphoxide) and slowly excreted in the urine.The drug is highly bound to plasma proteins.

5.2 Pharmacokinetic properties
Promethazine is well absorbed after oral administration, peak plasma concentration occurring in 2-3 hours.It is widely distributed in the boldy.It enters the brain and crosses the placenta.Phenothiazines pass into the milk at low concentrations.

5.3 Pre-clinical Safety:
None stated.

6. Pharmaceutical Particulars:

List of Excipients:

Maize starch	BP
Dibasic Calcium Phosphate	BP
Microcrystalline Cellulose	BP
Povidone K 30	BP
Sodium Starch Glycolate	BP
Magnesium Stearate	BP
Purified Talc	BP
Colloidal anhydrous silica	BP

6.2 Incompatibilities: Nil

6.3 Shelf Life: 36 months.

6.4 Special Precautions for storage:
Store below 30°C in a dry place. Protect from light.

6.5 Nature and contents of container:
Alu-PVC Blister of 20 tablets, such 5 Blisters are packed in a primary carton along with Pack insert.

6.6 Special precautions for disposal and other handling:
Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing Authorization Holder: TEKA PHARMACEUTICAL CO.LTD

8. Marketing Authorization Number: ---

9. Date of first Authorization / renewal of the authorization: ---

10. Date of revision of text: July 2020