Module 1- Administrative information and prescribing information

1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Enclosed

Summary Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Promethazine Teoclate Tablets BP 25 mg

1.1 Strength

Each uncoated tablet contains:
Promethazine Teoclate BP 25 mg
Excipients…….....q.s.

1.2 Pharmaceutical form

Uncoated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No	Ingredients	Spec	Qty/tab (mg)	Category
Dry Mixing				
1.	Promethazine Teoclate	BP	25.00	Active
2.	Maize Starch	BP	110.00	Diluent
3.	Lactose Anhydrous	BP	65.00	Diluent
Binding				
4.	P.V.P.K-30	BP	17.00	Binder
5.	Isopropyl Alcohol**	BP	80.00	Solvent
Lubrication				
6.	Magnesium stearate	BP	10.00	Lubricant
7.	Cross Carmellose sodium	BP	13.00	Disintegrant
8.	Purified Talcum	BP	5.00	Glidant
Total Weight			**245.00 mg**	

BP: British Pharmacopoeia

3. PHARMACEUTICAL FORM

White colored round shaped uncoated tablet having brake line on one side and plain on other side.

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

PROMETHAZINE TEOCLATE TABLETS 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. PROMETHAZINE TEOCLATE TABLETS should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days. Use in children: PROMETHAZINE TEOCLATE TABLETS 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 PROMETHAZINE TEOCLATE TABLETS. 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.
PROMETHAZINE TEOCLATE TABLETS 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.
PROMETHAZINE TEOCLATE TABLETS may interfere with immunologic urine pregnancy tests to produce false-positive or false-negative results. PROMETHAZINE TEOCLATE TABLETS 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 Fertility, 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 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 PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: H03BB
Pharmacotherapeutic group: Sulfur-containing imidazole derivatives
Mechanism of action:
Carbimazole, a thionamide, is a pro-drug which undergoes rapid and virtually complete metabolism to the active metabolite, thiamazole, also known as methimazole. The method of action is believed to be inhibition of the organification of iodide and the coupling of iodothyronine residues which in turn suppress the synthesis of thyroid hormones.

5.2 Pharmacokinetic properties

Absorption
Carbimazole is rapidly metabolised to thiamazole. After oral ingestion, peak plasma concentrations of thiamazole, the active moiety, occur at 1 to 2 hours.
Distribution
The total volume of distribution of thiamazole is 0.51/kg. Thiamazole is concentrated in the thyroid gland. This intrathyroidal concentration of thiamazole has the effect of prolonging its activity. However, thiamazole has a shorter half-life in hyperthyroid patients than in normal controls and so more frequent initial doses are required while the hyperthyroidism is active.
Biotransformation
Thiamazole is moderately bound to plasma proteins.
Carbimazole has a half-life of 5.3 to 5.4 hours. It is possible that the plasma half-life may also be prolonged by renal or hepatic disease. Thiamazole crosses the placenta and appears in breast milk. The plasma milk ratio approaches unity.
Elimination
Over 90% of orally administered carbimazole is excreted in the urine as thiamazole or its metabolites. The remainder appears in faeces. There is 10% enterohepatic circulation.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch	BP
Lactose Anhydrous	BP
P.V.P.K-30	BP
Isopropyl Alcohol	BP
Magnesium stearate	BP
Cross Carmellose sodium	BP
Purified Talcum	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a dry place below 30 ℃, Protect from light.

6.5 Nature and contents of container

10 x 10 Alu-PVC Blister Pack

6.6 Special precautions for disposal and other handling

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES

MARKETING AUTHORISATION HOLDER
First Vadis Pharmaceutical Industries Limited
Plot IN/2 Phase 2 Extension, Emene
Industrial Layout Enugu State

MANUFACTURED
First Vadis Pharmaceutical Industries Limited
Plot IN/2 Phase 2 Extension, Emene
Industrial Layout Enugu State

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION

10. DATE OF REVISION OF THE TEXT