Promethazine Teoclate 25mg Tablets

PL 15833/0028

UKPAR

TABLE OF CONTENTS

Lay summary Page 2
Scientific discussion Page 3
Steps taken for assessment Page 9
Summary of product characteristics Page 10
Patient information leaflet Page 16
Labelling Page 18
PROMETHAZINE TEOCLATE 25MG TABLETS

PL 15833/0028

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation (licence) for the medicinal product Promethazine TEOCLATE 25mg Tablets (product licence number: PL 15833/0028). Promethazine TEOCLATE 25mg Tablets are available from pharmacies without prescription.

Promethazine TEOCLATE 25mg Tablets are anti-emetic (anti-sickness) tablets which help to prevent and treat nausea and vomiting, including travel sickness and vertigo. Your doctor may prescribe this medicine for giddiness or light-headedness (vertigo), or for sickness after an operation, and in such cases the tablets should be taken as instructed by your doctor.

Promethazine TEOCLATE 25mg Tablets raised no clinically significant safety concerns and it was, therefore, judged that the benefits of using this product outweigh the risks; hence a Marketing Authorisation has been granted.
SCIENTIFIC DISCUSSION

TABLE OF CONTENTS

Introduction ........................................... Page 4
Pharmaceutical assessment ......................... Page 5
Preclinical assessment ............................... Page 6
Clinical assessment ................................ Page 7
Overall conclusions and risk benefit assessment Page 8
INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a Marketing Authorisation for the medicinal product Promethazine Teoclate 25mg Tablets to Manx Pharma Limited on 26 August 2010.

This is an abridged application submitted under Article 10(c) of EC Directive 2001/83, last paragraph. The applicant claims that this product is identical to Avomine 25mg Tablets (PL 15833/0003), which is also licensed by Manx Pharma Limited.

Promethazine Teoclate 25mg Tablets 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 Meniere’s syndrome, labyrinthitis and other causes.

No new data were submitted, nor was it necessary for this simple application, as the data are identical to those of the previously granted cross-reference product.
PHARMACEUTICAL ASSESSMENT

PROMETHAZINE TEOCLATE
The promethazine teoclate used in this product is identical to that used in the reference product and is, therefore, satisfactory.

DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT
The product contains lactose, sodium metabisulphite (E223), potato starch, dextrin, microcrystalline cellulose, stearic acid and magnesium stearate. The formulation of this product is identical to that of the already licensed cross reference product.

The tablets are stored in either blister packs of 10, 28 or 30 tablets; a Securitainer of 60 tablets; or a Securitainer or polyethylene bottle of 250 tablets. The blister comprises PVDC coated aluminium foil and PVDC coated UPVC. The bottle and Securitainer are comprised of high density polyethylene with low density polyethylene caps.

There appears to be no difference between the composition and packaging of the proposed product and those of the already licensed cross reference product.

The proposed shelf-life (5 years) and storage conditions (Store in the original container) are consistent with the details registered for the reference product.

ADDITIONAL DATA REQUIREMENTS
The manufacturing process, finished product specifications and active ingredient specification are in line with those for the reference product and are satisfactory.

Satisfactory TSE documentation has been provided for the lactose used in the tablets, no other materials of animal or human origin are used in the manufacturing process of the medicinal products.

The applicant is also the Marketing Authorisation Holder of the reference product. Letters of Access are, therefore, not required

EXPERT REPORTS
Satisfactory expert reports in the form of quality, non-clinical and clinical overall summaries are provided, with signed declarations from each expert confirming that the applicant’s product is identical to the reference product in all particulars. Expert CVs are also submitted and are acceptable.

PRODUCT LITERATURE
The proposed SPC, PIL and labels are identical to those for the reference product and are satisfactory.

ASSESSOR’S OVERALL CONCLUSIONS
A Marketing Authorisation may be granted for this product.
PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none is required for an application of this type.
CLINICAL ASSESSMENT

OVERVIEW
A statement has been provided confirming that the clinical particulars for Promethazine Teoclate 25mg Tablets are identical to those for the already licensed product; Avomine 25mg Tablets (PL 15833/0003). This is satisfactory.

BIOAVAILABILITY AND BIOEQUIVALENCE
No bioequivalence study has been performed to support this application and none is needed.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR’S OVERALL CONCLUSIONS
It is recommended that a Marketing Authorisation can be granted.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
Promethazine Teoclate 25mg Tablets are identical to the already licensed reference product, Avomine 25mg Tablets (PL 15833/0003), and are, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for applications of this type.

EFFICACY
The efficacy of promethazine teoclate is well established. The SPC, PIL and labelling are satisfactory and consistent with those for the cross-reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable, no significant preclinical or clinical safety concerns were identified, and benefit has been shown to be associated with promethazine teoclate. The risk benefit ratio is, therefore, considered to be acceptable.
PROMETHAZINE TEOCLATE 25MG TABLETS

PL 15833/0028

STEPS TAKEN FOR ASSESSMENT

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<td>1</td>
<td>The MHRA received the Marketing Authorisation application on 18 December 2009</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 29 December 2009</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the dossier on 26 April 2010</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s request, providing further information on the dossier on 10 June 2010</td>
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<td>Following assessment of the response the MHRA requested further information relating to the dossier on 19 July 2010</td>
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<td>6</td>
<td>The applicant responded to the MHRA’s request, providing further information on the dossier on 4 August 2010</td>
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<td>The application was determined on 28 August 2010</td>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Promethazine Teoclate 25mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Promethazine teoclate 25 mg.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Tablet.
White to pale cream, plain, circular biconvex tablets of 8.5 mm marked “PT” on one side with a score line on the reverse. The tablet can be divided into equal halves.

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 Meniere’s syndrome, labyrinthitis and other causes.

4.2 Posology and method of administration
Motion sickness

Adults

For the prevention on long journeys: one 25 mg tablet each evening at bedtime, starting the day before setting out. The duration of action is such that a second dose in 24 hours is not often necessary.

For the prevention of motion sickness on short journeys: one 25 mg tablet one or two hours before travelling or as soon after as possible.

Treatment of motion sickness: One 25 mg tablet as soon as possible and repeated the same evening followed by a third tablet the following evening.

Nausea and vomiting due to other causes

Adults
One 25 mg tablet at night is often sufficient, but two or three tablets are sometimes necessary. Alternatively, more frequent administration such as 25 mg two or three times a day may be required for some patients. It is often not necessary to give more than four of the 25 mg Promethazine Teoclone tablets in 24 hours.

Children

In the above indications children over 10 years of age may be given the lower adult doses described above. Children between 5 and 10 years may be given half the adult dose. Tablets are not suitable for administration to children aged between 2 and 5 years. An oral liquid preparation is recommended in this age group. Not for use in children under 2 years of age (see section 4.3).

Elderly

No specific dosage recommendations.

*Administration:* Oral.

4.3 Contraindications
Promethazine Teoclone should not be used in patients with:
- Hypersensitivity to promethazine or any of the excipients
- Hypersensitivity to other phenothiazines
- Coma or CNS depression of any cause

Promethazine Teoclone should not be used in children less than two years of age because of the potential for fatal respiratory depression.

Promethazine Teoclone should not be administered to patients who have been taking monoamine oxidase inhibitors within the previous 14 days.

4.4 Special warnings and precautions for use
Promethazine Teoclone may thicken or dry lung secretions and impair expectoration, it should therefore be used with caution in patients with asthma, bronchitis or bronchiecteses. 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 pyloro-duodenal obstruction.

Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs eg. Salicylates.

Promethazine may also delay the early diagnosis of intestinal obstruction or raised intracranial pressure through suppression of vomiting

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye’s syndrome.
Promethazine Teoclate should not be used for longer than seven days without seeking medical advice.

Contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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 pregnancy tests to produce false-positive and false-negative results.

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

4.6 Pregnancy and lactation
Use in 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 weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

Use in lactation: Available evidence suggests that the amount excreted in milk is insignificant. However, there are risks of neonate irritability and excitement.

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
Side-effects may be seen in a few patients: drowsiness, dizziness, restlessness, headaches, nightmares, tiredness and disorientation. Anticholinergic side-effects such as blurred vision, dry mouth and urinary retention occur occasionally. Newborn and premature infants are susceptible to the anticholinergic effects of promethazine, while other children may display paradoxical hyperexcitability. The elderly are particularly susceptible to the anticholinergic effects and confusion may occur.

Other side-effects include anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, muscle spasms and tic-like movements of the head and face. Anaphylaxis, jaundice and blood dyscrasias including haemolytic anaemia rarely occur. Photosensitive skin reactions have been reported; strong sunlight should be avoided during treatment.
4.9 Overdose

Symptoms
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 characterised 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 occurrence. Cardiac conduction abnormalities and dysrhythmias may occur; cardiorespiratory depression is uncommon. Patients who have been unconscious may be hypothermic.

Treatment
Consider use of activated charcoal only if the patient presents within one hour of ingestion. Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with intravenous diazepam and delirium treated with oral diazepam or other suitable anticonvulsant. Arrhythmias may be treated by correction of hypoxia, acidosis and other biochemical abnormalities. The use of antiarrhythmic drugs to treat dysrhythmias should be avoided. Procyclidine injection may be effective in the treatment of dystonic reactions.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
ATC Code: R06AD02
Promethazine teocluate is a long acting antihistamine with anti-emetic, central sedative and anticholinergic properties.

Promethazine is metabolised 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 concentrations occurring in 2-3 hours. It is widely distributed in the body. It enters the brain and crosses the placenta. Phenothiazines pass into the milk at low concentrations.

5.3 Preclinical safety data
None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Lactose
Sodium metabisulphite (E223)
Potato starch
Dextrin
Microcrystalline cellulose
Stearic acid
Magnesium stearate

6.2 Incompatibilities
None.

6.3 Shelf life
Five (5) years.

6.4 Special precautions for storage
Store in the original container.

6.5 Nature and contents of container
Blister pack of 10 x 25 mg tablets.
Blister pack of 28 x 25 mg tablets.
Blister pack of 30 x 25 mg tablets.
Securitainer of 60 x 25 mg tablets.
Securitainer or polyethylene bottle of 250 x 25 mg tablets.

The blister comprises PVDC coated aluminium foil, 20 micron thick and PVDC coated UPVC.

The bottle and securitainer are comprised of high density polyethylene with low density polyethylene caps.

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
Manx Pharma Limited
Taylor Group House
Wedgnock Lane
Warwick
CV34 5YA
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)
PL 15833/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
26/08/2010
DATE OF REVISION OF THE TEXT
26/08/2010
PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET - INFORMATION FOR THE USER

Promethazine Teoclolate 25mg Tablets

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Promethazine Teoclolate Tablets carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Promethazine Teoclolate Tablets are and what they are used for
2. Before you take Promethazine Teoclolate Tablets
3. How to take Promethazine Teoclolate Tablets
4. Possible side effects
5. How to store Promethazine Teoclolate Tablets
6. Further information

1. What Promethazine Teoclolate Tablets are and what they are used for

Promethazine Teoclolate 25mg Tablets (hereinafter referred to as Promethazine Teoclolate Tablets) are an anti-emetic (anti-sickness drug) which help to prevent, and treat nausea and vomiting, including travel sickness, and vertigo.

Promethazine Teoclolate Tablets contain promethazine which belongs to a group of medicines called phenothiazines. Your doctor may prescribe this medicine for giddiness or light-headedness (vertigo), or for sickness after an operation, and in such cases the tablets should be taken as instructed by your doctor.

2. Before you take Promethazine Teoclolate Tablets

Do not give to a child under 2 years old.

Do not take Promethazine Teoclolate Tablets if you have or have had:

- an allergic reaction to promethazine, any phenothiazine or any of the ingredients (see section 6 for more details)
- taken medicines for depression, known as Monoamine Oxidase Inhibitors (MAOIs) within the last 14 days
- CNS depression, people with CNS depression will seem sleepy or unconscious (including coma).

Take special care with Promethazine Teoclolate Tablets and tell your doctor or pharmacist if you suffer with:

- glaucoma (increased pressure in the eye)
- epilepsy

- heart problems
- liver problems
- kidney or bladder problems
- a chest condition such as asthma or bronchitis
- severe headaches with blurred vision, severe stomach pains with vomiting, dizziness, difficulty with keeping your balance, ringing in the ears or other ear problems as well as feeling sick
- a bad cough
- Reye's Syndrome or symptoms of Reye's Syndrome (including persistent vomiting, feeling tired or sleepiness).

Do not take Promethazine Teoclolate Tablets for more than 7 days without contacting your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

You must tell your doctor or pharmacist if you are already taking any of the following medicines:

- anticholinergic agents
- medicines to help you sleep (hypnotics)
- medicines for depression, mental illness or anxiety (tricyclic antidepressants, sedatives)
- medicines for crampy stomach pains, Parkinson's disease or bladder problems.

If you are having skin tests for allergy, do not take this medicine as it interferes with the results. You should stop taking this medicine at least 72 hours before the skin tests.

Taking Promethazine Teoclolate Tablets with food and drink

While taking Promethazine Teoclolate Tablets, you should avoid drinking alcohol as the tablets will add to the effects of alcohol.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are breast-feeding your baby, you should not take Promethazine Teoclolate Tablets, unless they have been recommended for you by a doctor. If you are breast-feeding your baby, Promethazine Teoclolate Tablets may cause your baby to be irritable and excited.

If you are having a pregnancy test, do not take this product as it interferes with the results.

Driving and operating machinery

These tablets may make you feel dizzy, sleepy, disorientated or confused or cause you to have a headache. You should not drive or operate machinery for the first few days, and until you are sure that you are not affected by these unwanted effects.

(continued overleaf)
Important information about some of the ingredients in this product
These tablets contain sodium metabisulphite which may rarely cause hypersensitivity (allergic) reactions and bronchospasm (difficulty breathing). These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

3. How to take Promethazine Teoclate Tablets

Always take Promethazine Teoclate Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The usual dose is:

**Adults**
For the prevention of travel sickness on long journeys
Take one tablet each night at bedtime starting the night before you travel.

For the prevention of travel sickness on short journeys
Take one tablet one or two hours before travelling.

**Treatment of travel sickness**
Take one tablet as soon as you feel sick followed by a second tablet the same evening. Take a third tablet the next evening if necessary.

**Nausea and vomiting due to other causes**
One tablet each night is usually enough, but two or three tablets may be required by some patients. These can be taken at intervals during the day, but it is often not necessary for more than 4 tablets to be needed in any 24 hour period.

**Children over 10 years old**
Give the lower adult dose (one tablet).

**Children 5 - 10 years old**
Give half the lower adult dose (half a tablet).

**Do not take Promethazine Teoclate Tablets for more than seven days. Should symptoms persist for or do not improve after 7 days, talk to your doctor or pharmacist.**

**Promethazine Teoclate Tablets are not suitable for children under 2 years of age.**
Avoid strong sunlight while taking this product as your skin may be more sensitive to the effect of the sun.

If you take more Promethazine Teoclate Tablets than you should:
Talk to your doctor or pharmacist immediately.

If you forget to take Promethazine Teoclate Tablets
If you forget to take a tablet, take one as soon as you remember. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects
Like all medicines Promethazine Teoclate Tablets can cause side effects, although not everybody gets them. If you experience any of the following side effects speak to your doctor immediately:

- shortness of breath or difficulty breathing
- irregular heartbeats, low blood pressure (light-headed feeling when standing).

If you notice any of the following side effects speak to your doctor or pharmacist:
- infections, fevers or sore throats which seem to go on a long time
- unexplained bruising or nose bleeds
- if you develop a yellow colour of your skin, dark urine and yellowing of the whites of the eyes.

Other side effects may include:
- headache, dizziness, restlessness, confusion, you may feel tired or sleepy
- children may become over excited while taking this product
- occasionally some people, especially the elderly may experience blurred vision, dry mouth or have difficulty passing water
- loss of appetite, upset stomach, nightmares
- cramp or muscles twitching or jerking, or the muscles become rigid
- unusual movements of the head and face muscles.

If any of these side effects gets serious, or if you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.

5. How to store Promethazine Teoclate Tablets
Keep this product out of the reach and sight of children. Do not use after the expiry date printed on your pack. Store in the original container. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information
What Promethazine Teoclate Tablets contain
Each tablet contains the active ingredient promethazine teoclate 25mg.
Promethazine Teoclate Tablets also contain: lactose, sodium metabisulphite (E223), potato starch, dextrin, microcrystalline cellulose, stearic acid and magnesium stearate.

What Promethazine Teoclate Tablets look like and contents of the pack
Promethazine Teoclate Tablets are white to pale cream, plain, circular biconvex tablets marked ‘PT’ on one side with a score line on the reverse. They are available in cartons of 10 or 28 tablets and plastic containers of 60 tablets.

Marketing Authorisation Holder:
Manx Pharma Ltd., Taylor Group House, Wedgock Lane, Warwick, CV34 5YA, United Kingdom.

Manufacturer:
Manx Healthcare Ltd., Taylor Group House, Wedgock Lane, Warwick, CV34 5YA, United Kingdom.

This leaflet was revised in July 2010
LABELLING

Blister:
Promethazine Teoclolate 25mg Tablets
For the prevention and relief of travel sickness, general nausea and vertigo
Active ingredient: Each tablet contains 25mg promethazine teoclolate. Other ingredients include: lactose, sodium metabisulphite (E223).
DOSAGE: 1 to 4 tablets per day. For oral use. Adults: For the prevention of travel sickness on long journeys: Take one tablet each night at bedtime starting on the night before you travel. For the prevention of travel sickness on short journeys: Take one tablet one or two hours before travelling. If you forget to take a tablet, take one as soon as you remember. Treatment of travel sickness: Take one tablet as soon as you feel sick followed by a second tablet the same evening. Take a third tablet the next evening if necessary. Nausea and vomiting due to other causes: One tablet each night is usually enough, but two or three tablets may be required by some patients. These can be taken at intervals during the day, but it is often not necessary for more than 4 tablets to be needed in any 24 hour period. For vertigo or sickness after an operation: These tablets should be taken as instructed by your doctor. Children over 10 years old: Give the lower adult dose (one tablet). Children 5 - 10 years: Give half the lower adult dose (half a tablet). Keep out of the reach & sight of children. If you take more Promethazine Teoclolate Tablets than you should: talk to your doctor or pharmacist immediately. Not to be taken during pregnancy unless recommended by your doctor. Patients taking other medicines should consult their doctor before taking Promethazine Teoclolate Tablets. Please see enclosed leaflet for further information. Store in the original container.

Warning: May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink.

PL 15833/0028  WIP:URN:078510-XXX-LBF-01

MANX Pharma Ltd. Distributed by MANX Healthcare Ltd. Both at Taylor Group House, Wedgwick Lane, Warwick CV34 5YA, UK.

Batch No.
Expiry Date
Promethazine Teoclolate 25mg Tablets

For the prevention and relief of travel sickness, general nausea and vertigo.

Dosage:

Adults: 1 to 4 tablets per day, for oral use.

For the prevention of travel sickness on long journeys: Take one tablet each night before bedtime starting on the night before you travel.

For the prevention of travel sickness on short journeys: Take one tablet one or two hours before travelling. If you forget to take a tablet, take one as soon as you remember.

Treatment of travel sickness: Take one tablet as soon as you feel sick followed by a second tablet the same evening. Take a third tablet the next evening if necessary.

Nausea and vomiting due to other causes: One tablet each night is usually enough, but two or three tablets may be required by some patients. These can be taken at intervals during the day, but it is often not necessary for more than 4 tablets to be needed in any 24 hour period.

For vertigo or sickness after an operation: These tablets should be taken as instructed by your doctor.

Children over 10 years old: Give the lower adult dose (half a tablet).

Children 5–10 years: Give half the lower adult dose (half a tablet).

Keep out of the reach and sight of children.

If you take more Promethazine Teoclolate Tablets than you should tell your doctor or pharmacist immediately.

Not to be taken during pregnancy unless recommended by your doctor. Patients taking other medicines should consult their doctor before taking Promethazine Teoclolate Tablets.

Warning: May cause drowsiness. If affected do not drive or operate machinery.

Avoid alcoholic drinks.

Active ingredient: Each tablet contains 25mg Promethazine teoclolate.

Other ingredients include: lactose, sodium metabisulphite (E223).

Please see enclosed leaflet for further information.

Store in the original container.