. Name of the medicinal product

KOYOMINE TABLETS

2. Qualitative and quantitative composition

EACH UNCOATED TABLET CONTAINS

PROMETHAZINE TEOCLATE .....25MG.

3. Pharmaceutical form

White circuler uncoated tablets having embossed with “KOYOMINE” on one side and breakline on other side of tablets.

4. Clinical particulars

4.1 Therapeutic indications

As symptomatic treatment for allergic conditions of the upper respiratory tract and skin including allergic rhinitis, urticaria and anaphylactic reactions to drugs and foreign proteins.

As an antiemetic.

For short term use:

Treatment of insomnia in adults.

For short term use as a paediatric sedative.

4.2 Posology and method of administration

Route of administration: Oral.

Not for use in children under the age of 2 years (see section 4.3).

As an antihistamine in allergy:

Children 2-5 years	The use of Koyomine Elixir is recommended for this age group.
Children 5-10 years	25 mg as a single dose*. Maximum daily dose 25 mg.
Children over 10 years and adults (including elderly)	25 mg as a single dose*. Increasing to a maximum of 25 mg bd as required.

*Single doses are best taken at night.

As an antiemetic:

Children 2-5 years	The use of Koyomine Elixir is recommended for this age group.
Children 5-10 years	The use of Koyomine Elixir or Koyomine 10 mg Tablets is recommended.
Children over 10 years and adults (including elderly)	25 mg to be taken the night before the journey. To be repeated after 6–8 hours as required.

As a paediatric sedative for short term use and for short term treatment of insomnia in adults:

Children 2-5 years	The use of Koyomine Elixir is recommended for this age group.
Children 5-10 years	25 mg as a single night time dose.
Children over 10 years and adults (including elderly)	25 or 50 mg as a single night time dose.

4.3 Contraindications

Koyomine should not be used in patients in coma or suffering from CNS depression of any cause.

Koyomine should not be given to patients with a known hypersensitivity to promethazine or to any of the excipients.

Promethazine is contraindicated for use in children less than two years of age because of the potential for fatal respiratory depression..

Koyomine should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

4.4 Special warnings and precautions for use

Koyomine may thicken or dry lung secretions and impair expectoration. It should therefore be used with caution in patients with asthma, bronchitis or bronchiectasis.

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.

The use of promethazine should be avoided in children and adolescents with signs and symptoms suggestive of Reye's Syndrome.

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.

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

Koyomine should not be used for longer than 7 days without seeking medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

Koyomine will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment. Koyomine may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results. Koyomine should be discontinued at least 72 hours before the start of skin tests as it may inhibit the cutaneous histamine response thus producing false-negative results.

4.6 Fertility, pregnancy and lactation

Koyomine should not be used in pregnancy unless the physician considers it essential. The use of Koyomine is not recommended in the 2 weeks prior to delivery in view of the risk of irritability and excitement in the neonate.

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

4.7 Effects on ability to drive and use machines

Because the duration of action may be up to 12 hours, patients should be advised that if they feel drowsy they should not drive or operate heavy machinery.

4.8 Undesirable effects

The following CIOMS frequency rating is used: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1000 to <1/100); rare (≥1/10 00 to <1/1000); very rare (<1/10 000), not known (cannot be estimated from the available data).

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. 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 due to promethazine. Other side-effects include urticaria, rash, pruritus, anorexia, gastric irritation, palpitations, hypotension, arrhythmias, extrapyramidal effects, restless legs syndrome, 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.

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 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

Symptoms of severe overdosage are variable. They are characterised in children by various combinations of excitation, ataxia, incoordination, 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. Cardiorespiratory depression is uncommon. If the patient is seen soon enough after ingestion,

it should be possible to induce vomiting with ipecacuanha despite the antiemetic effect of promethazine; alternatively, gastric lavage may be used.

Treatment is otherwise supportive with attention to maintenance of adequate respiratory and circulatory status. Convulsions should be treated with diazepam or other suitable anticonvulsant.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antihistamines for systemic use; Phenothiazine derivatives, ATC code: R06AD02

Potent, long acting, antihistamine with additional anti-emetic central sedative and anti-cholinergic properties.

5.2 Pharmacokinetic properties
Promethazine is distributed widely in the body. It enters the brain and crosses the placenta. Promethazine is slowly excreted via urine and bile. Phenothiazines pass into the milk at low concentrations.

5.3 Preclinical safety data
No additional preclinical data of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients
Lactose monohydrate

Maize starch

Dibasic calcium phosphate

Magnesium stearate

Gelatin

Sodium methyl paraben
Sodium propyl paraben
Sodium starch Glycolate
Talcum
Aerosil (COLLOIDAL SILICON DIOXIDE IP)

6.2 Incompatibilities
Not applicable

6.3 Shelf life
3 years.

6.4 Special precautions for storage
Store in cool dark and dry place below 30°C protect from sunlight . Store in the original carton in order to protect from light.

6.5 Nature and contents of container
GOLDEN ORANGE COLOURED PVC (0.25X116MM)
aluminium foil (coated with vinyl heat seal lacquer) backing in cartons of 100 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements

7. Marketing authorisation holder

NKOYO CHEMISTS

NAFDAC NO. :- B4 -2798

112(L) x 42 mm

Prepared On : 02Feb2015

Repeat 28

Koyomine
Promethazine Teoclate
Tablets BP
Composition
Each tablet contains:
Promethazine Teoclate BP 25 mg
Dosage: As directed
by the Physician.
Store in a cool, dry &
dark place.
Keep all medicine out of
the reach of children.
Nafdac Reg. No.: B4-2798
Mfg. Lic. No. : KD-493
Sole Agent:
Nkoyo Chemists
18, Ukpor Street, Fegge,
Onitsha, Anambra State, Nigeria.
Manufactured By:
Mancare
PHARMACEUTICALS PVT. LTD.
Plot No. 59, 60, 85, 86, V.M.I.E, Dowali Village
Vasai (W), Dist. Thane, Maharashtra, India.

Koyomine
Promethazine Teoclate
Tablets BP
Composition
Each tablet contains:
Promethazine Teoclate BP 25 mg
Dosage: As directed
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Store in a cool, dry &
dark place.
Keep all medicine out of
the reach of children.
Nafdac Reg. No.: B4-2798
Mfg. Lic. No. : KD-493

For the use of Registered medical Practitioner or a Hospital or a Laboratory only.

Koyomine 25mg *Promethazine Teoclate Tablets BP*

COMPOSITION
Each tablet contains:
Promethazine Teoclate BP.....25 mg

PROPERTIES
Antihistmine, Antinauseant & Antiemetic

INDICATIONS
Although the primary indication for Koyomine is the prevention and treatment of motion sickness, it has been used in the treatment and prevention of nausea and vomiting due to other causes , including, vestibular disturbance, drug intolerance, migraine, infectious and radiation therapy.

CONTRAINDICATIONS
Koyomine 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 phenothiazines. Koyomine should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days.
Use in children: Koyomine should not be used in children less than two years of age.

DOSAGE AND ADMINISTRATION
ADULTS_TRAVEL SICKNESS
PREVENTION: For long journeys, 1 tablet each night at bedtime commencing on the night before travelling. For 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. It is seldom necessary to give more than 4 tablets in 24 hours or to repeat a dose in less thess 8 hours.
NAUSEA AND VOMITING DUE TO OTHER CAUSES: 1 tablet repeated as required. Often 1 tablet at bedtime is sufficient . The maximum dose in 24 hours is 100 to 150 mg (4 to 6 tablets) in divided doses.
CHILDREN
TRAVEL SICKNESS,NAUSEA AND VOMITING DUE TO OTHER CAUSES
Koyomine should not be used in paediatric patients less then two yearsof age.
3 to 5 years: one quarter the corresponding adult dous; 5 to 10 years: one half the corresponding adult dous; over 10 years: corresponding adult dous.

PRECAUTIONS
Care is necessary with patients who take anticholinergic agents, tricyclic antidepressants, sedatives or hypnotics, as such agents are enhanced by Koyomine. It should be used with caution
in patients with asthma , bronchitis or bronchiectesis. Promethazine may mask the warning signs of ototoxicity caused by ototoxic drugs; e.g.salicylates.
Koyomine may interfere with immunologic urine pregnancy tests to produce
False- positive or false-negative results.

USE IN PREGNANCY(CATEGORY C)
When given in high doses during late pregnancy, phenothiazines have caused prolonged extrapyramidal disturbances in the child. There is inadequate evidence of safety of the drug in human pregnancy.

ADVERSE REACTIONS
Dry mouth, epigastric distress, loss of appetite , nausea, vomiting, diarrhoea, constipation, sedation, restlessness, dizziness, lassitude, incoordination, fatigue and blurred vision may occur. Tinnitus, tachycardia, bradycardia, faintness, palpitations, hypotension and arrhythmias are some less commonly occurring reactions.

OVERDOSAGE
The chief symptom of acute poisoning from the ingestion of promethazine is unconsciousness which is, however, commonly delayed. In addition, convulsions have
Occurred, with unconsciousness in the intervening periods. An immediate first aid measure is to induce vomiting mechanically or to give an emetic, the value of which, however, is limited by the antiemetic antivity of Koyomine once absorbed . The most important step in treatment must be, to remove as much as Possible of the unabsorbed, material by means of gastric lavage with warm sodium bicarbonate solution.

STORAGE
Store in a cool, dry & dark place.
Keep all medicines out of reach of children.

PRESENTATION
Pack of 5 x 20 tablets

Mfg. Lic. No. : KD-493
Nafadac Reg. No. : B4-2798

Manufactured By :
Mancare
PHARMACEUTICALS PVT. LTD.
Plot No. 59, 60, 85, 86, V.M.I.E, Dowali Village,
Vasai (W), Dist. Thane, Maharashtra, India.
E-mail: mancerp@yahoo.co.in

Sole Agent:
Nkoyo Chemists
18, Ukpor Street, Fegge, Onitsha,
Anambra State, Nigeria.

100x 110mm

Prepared On :02Feb2014