SUMMARY OF PRODUCTS CHARACTERISTICS

1.NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Promezin Syrup**
1.2 Generic Name : **Promethazine Oral Solution BP**
1.3 Strength : **5mg/5ml**
1.4 Pharmaceutical Form: **Syrup**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each 5ml contains:
Promethazine Hydrochloride BP 5mg
Flavored Base q.s.
Color: Caramel

3. PHARMACEUTICAL FORM

Syrup (Liquid oral); Light brown colored flavored palatable syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Promezin Syrup is indicated for symptomatic relief of allergy such as hay fever and urticaria, Insomnia associated with urticaria and pruritus, Sedation (short-term use), Nausea, Vomiting, Vertigo, Labyrinthine disorders, Motion sickness.

4.2 Posology and method of administration

- **Symptomatic relief of allergy such as hay fever and urticaria | Insomnia associated with urticaria and pruritus:**
  Child 2–4 years: 5 mg twice daily, alternatively 5–15 mg once daily, dose to be taken at night.
  Child 5–9 years: 5–10 mg twice daily, alternatively 10–25 mg once daily, dose to be taken at night.
  Child 10–17 years: 10–20 mg 2–3 times a day, alternatively 25 mg once daily, dose to be taken at night, increased if necessary to 25 mg twice daily.
  Adult: 10–20 mg 2–3 times a day.
- **Sedation (short-term use):**
  Child 2–4 years: 15–20 mg
  Child 5–9 years: 20–25 mg
  Child 10–17 years: 25–50 mg
  Adult: 25–50 mg
- **Nausea, Vomiting, Vertigo, Labyrinthine disorders, Motion sickness:**
  Child 2–4 years: 5 mg, to be taken at bedtime on night before travel, repeat following morning if necessary
  Child 5–9 years: 10 mg, to be taken at bedtime on night before travel, repeat following morning if necessary.
  Child 10–17 years: 20–25 mg, to be taken at bedtime on night before travel, repeat following morning if necessary
  Adult: 20–25 mg, to be taken at bedtime on night before travel, repeat following morning if necessary.

4.3 Contraindications:

Promethazine should not be given to children under 2 years, except on specialist advice, because the safety of such use has not been established.

4.4 Special warnings and special precautions for use:

Caution should be taken in epilepsy, prostatic hypertrophy (in adults), pyloroduodenal obstruction, severe coronary artery disease, susceptibility to angle-closure glaucoma, urinary retention.

MHRA/CHM ADVICE (MARCH 2008 AND FEBRUARY 2009) OVERTHE-COUNTER COUGH AND COLD MEDICINES FOR CHILDREN Children under 6 years should not be given over-thecounter cough and cold medicines containing promethazine.

4.5 Interaction with other FPPs and Other forms of Interaction

Promethazine will enhance the action of any anti-cholinergic agent, tricyclic antidepressant, sedative or hypnotic. Alcohol should be avoided during treatment. Promethazine may interfere with immunological urine pregnancy tests to produce false-

positive or false-negative results. Promethazine 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 Pregnancy and lactation

Avoiding use of Promethazine during pregnancy; however, there is no evidence of teratogenicity. Use in the latter part of the third trimester may cause adverse effects in neonates such as irritability, paradoxical excitability, and tremor.

Most antihistamines are present in breast milk in varying amounts; although not known to be harmful, advise avoiding their use in mothers who are breast-feeding.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Arrhythmia, blood disorder, confusion, dizziness, drowsiness, dry mouth, headache, hypotension jaundice, movement disorders, palpitations, photosensitivity reaction, urinary retention, vision blurred, agranulocytosis, angle closure glaucoma, anticholinergic syndrome, anxiety, insomnia, leucopenia, nasal congestion, nausea, rash, seizure, thrombocytopenia, tinnitus, tremor, vomiting elderly patients are more susceptible to anti-cholinergic side-effects.

4.9 Overdose

Symptoms of overdose may include 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-histaminic

ATC Code: R06AD02

Mechanism of action:

Promethazine, a phenothiazine, is an H1-antagonist with anticholinergic, sedative, and antiemetic effects and some local anesthetic properties. Promethazine is used as an antiemetic or to prevent motion sickness. Like other H1-antagonists, promethazine competes with free histamine for binding at H1-receptor sites in the GI tract, uterus, large blood vessels, and bronchial muscle. The relief of nausea appears to be related to central anticholinergic actions and may implicate activity on the medullary chemoreceptor trigger zone.

5.2 Pharmacokinetic properties

On average, 88% of a promethazine dose is absorbed after oral administration; however, the absolute bioavailability is only 25% because of first-pass clearance. 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

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Ingredients	Spec.
Sucrose (Pharma grade)	BP
Liquid Sorbitol (Sorbitol Solution 70%)	BP
Propylene Glycol	BP
Acesulfame Potassium	BP
Butylated Hydroxyanisole (BHA)	BP
Benzoic Acid	BP
Monothioglycerol (90 %)	USP
Colour Caramel	IH
Essence Pineapple INT. 22768	IH
Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

18month from the date of manufacturing.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep out of reach of Children. Keep container tightly closed.

6.5 Nature and contents of container

100ml solution in amber colored PET bottle in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

06848/07039/REN/2019

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Nov 28, 2021

10. DATE OF REVISION OF THE TEXT
