1. Name of product

Emzor Promethazine HCl 5 mg/5 mL Syrup

2. Qualitative and quantitative composition

Each 5ml of the syrup contains promethazine Hydrochloride BP 5

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Oral solution

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.
- Prevention and control of nausea and vomiting.
- Active and prophylactic treatment of motion sickness.
- For short term use as a paediatric sedative.

4.2 Posology and method of administration

Age	As an antihistamine in allergy	As an Antiemetic	Short term sedation
Children 2-5 years	5ml-15ml as a single dose. Or 5ml two daily	5ml to be taken the night before the journey. To be repeated after 6-8 hours as required.	15ml or 20ml as a single night time dose.

Method of administration

For oral administration

Contraindication

Promethazine must not be given to neonates, premature infants or patients hypersensitive to phenothiazines.

Not for use in children under the age of 2 years because the safety of such use has not been established.

Warnings/Precautions

- It should be used with caution in patients with asthma,bronchitis or bronchiectasis.
- It should be used with care in patient with epilepsy or hepatics and renal insufficiency.
- Promethazine should not be used for longer than 7 days without seeking medical advice.
- It should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

4.3 Drug Interactions

Promethazine will enhance the action of any anticholinergic agent, tricyclic,antidepressant, sedative or hypnotic.

4.3 Pregnancy and Lactation

Promethazine should not be used in pregnancy unless the physician considers it essential. The use of Promethazine 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.

4.5 Effects on ability to drive and use machines

Because the duration of action may be to 12 hours, patient should be advice that if they feel drowsy they should not drive or operate heavy machinery

4.6 Undesirable effects

Side effects may be seen in few patients such as drowsiness, restlessness, headaches, nightmares, tiredness and disorientation.

4.7 Overdose

The patient is seen enough after ingestion, it should be possible to reduce 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 suitable anticonvulsant.

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, muscle spasms and tic-like movements of the head and face. Anaphylaxis, jaundice and blood dyscrasias including haemolyticanaemia rarely occur. Photosensitive skin reactions have been reported. Strong sunlight should be avoided during treatment.

<u>Reporting of suspected adverse reactions</u>

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.

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 anticholinergic 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 concentration.

5.3 Preclinical safety data

No additional preclinical data of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of Excipients

Promethazine Hydrochloride

Sodium Saccharin

Sucrose

Citric Acid

Sodium citrate

Methyl Paraben

Propyl Paraben

Sodium CMC (Medium viscosity)

Sodium Metabisulphite

Sodium sulphite

Caramel Flavour

Banana Flavour

Ethanol 96%

Purified Water (to volume)

Incompatibilities

None stated.

6.2 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C. Store in the original carton in order to protect from light.

6.3 Special precautions for storage

Store below 25°C. Keep the bottle in the outer carton in order to protect from light.

6.5 Nature and contents of container

PVC Aluminium Pack.

Pack Size: 7, 14, 28, 30, 50, 60, 100 and 500 film coated tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing authorization holder

Emzor Pharmaceutical Industries Limited.

Sagamu/Benin Expressway, Makun, Sagamu Local Govt, Ogun state.

8. Marketing authorization number(s)

N/A

9. Date of first authorization/renewal of authorization

N/A

10. Date of revision of text

N/A