**1. Name of the medicinal product**
Alben Promethazine Syrup 5mg/5ml Oral Solution

**2. Qualitative and quantitative composition**
Each 5ml of solution contains 5 mg of the active substance promethazine hydrochloride.

Excipient(s) with known effect:

For the full list of excipients see section 6.1.

**3. Pharmaceutical form** Oral Solution

Clear, golden, syrupy liquid.

**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 | Either 5–15 mg as a single dose.<br>Or 5 mg bd.<br>Maximum daily dose 15 mg. |
| Children 5-10 years | Either 10–25 mg as a single dose.<br>Or 5-10 mg bd.<br>Maximum daily dose 25 mg. |
| Children over 10 years and adults (including elderly) | Initially 10 mg bd.<br>Increasing to a maximum of 20 mg tds as required. |

***As an antiemetic:***

| | |
|---|---|
| Children 2-5 years | 5 mg to be taken the night before the journey. To be repeated after 6–8 hours as required. |
| Children 5-10 years | 10 mg to be taken the night before the journey. To be repeated after 6–8 hours as required. |
| 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 | 15 or 20 mg as a single night time dose. |
| Children 5-10 years | 20 or 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. |
| | The use of Alben Promethazine Syrup tablets to provide these doses is recommended. |

**4.3 Contraindications**

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

Alben Promethazine Syrup 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.

Alben Promethazine Syrup should be avoided in patients taking monoamine oxidase inhibitors up to 14 days previously.

**4.4 Special warnings and precautions for use**

Alben Promethazine Syrup 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.

Alben Promethazine Syrup Elixir should not be used for longer than 7 days without seeking medical advice.

If you have diabetes, you should be aware that Alben Promethazine Syrup Elixir contains sugar, which the body will convert into small amounts of sugar. The maximum 5ml single dose of Alben Promethazine Syrup Elixir is equivalent to approximately 3.3 grams of sugar. Taking this amount of Alben Promethazine Syrup Elixir is unlikely to affect the control of your diabetes or require you to increase your diabetes medication.

Alben Promethazine Syrup Elixir contains sodium. The maximum 25ml single dose is equivalent to approximately 75mg of sodium. This should be taken into account if you are on a controlled sodium diet.

Alben Promethazine Syrup Elixir contains sodium sulphite anhydrous and sodium metabisulphite these may rarely cause severe hypersensitivity reaction and bronchospasm.

Phenothiazine derivatives may potentiate QT interval prolongation which increases the risk of onset of serious ventricular arrhythmias of the torsade de pointes type, which is potentially fatal (sudden death). QT prolongation is exacerbated, in particular, in the presence of bradycardia, hypokalaemia, and acquired (i.e., drug induced) QT prolongation. If the clinical situation permits, medical and laboratory evaluations should be performed to rule out possible risk factors before initiating treatment with a phenothiazine derivative and as deemed necessary during treatment (see section 4.8).

**4.5 Interaction with other medicinal products and other forms of interaction**
Alben Promethazine Syrup will enhance the action of any anticholinergic agent, tricyclic antidepressant, sedative, or hypnotic. Alcohol should be avoided during treatment. Alben Promethazine Syrup may interfere with immunological urine pregnancy tests to produce false-positive or false-negative results. Alben Promethazine Syrup 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.

Special caution is required when promethazine is used concurrently with drugs known to cause QT prolongation (such as antiarrhythmics, antimicrobials, antidepressants, antipsychotics) to avoid exacerbation of risk of QT prolongation. **4.6 Fertility, pregnancy and lactation**

Alben Promethazine Syrup Elixir should not be used in pregnancy unless the physician considers it essential. The use of Alben Promethazine Syrup 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, QT prolongation, torsade de pointes, 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.

The preservatives used in Alben Promethazine Syrup Elixir have been reported to cause hypersensitivity reactions, characterised by circulatory collapse with CNS depression in certain susceptible individuals with allergic tendencies.

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.

**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. Tachycardia may develop. Cardiorespiratory depression is uncommon. High doses (supratherapeutic doses) can cause ventricular arrhythmias including QT prolongation and torsade de pointes (see section 4.8). 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 another 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**

Citric acid monohydrate (E330)

Sodium citrate (E331)

Ascorbic acid (E300)

Sodium sulphite anhydrous (E221)

Sodium metabisulphite (E223)

Orange juice flavour 510844E

Caramel (E150)

Purified water

**6.2 Incompatibilities** None stated.

**6.3 Shelf life**

3 years when unopened.

**6.4 Special precautions for storage**

Store below 30°C. Keep the bottle in the outer carton in order to protect from light.

**6.5 Nature and contents of container**

Amber glass type III bottle containing 60 ml. Closed by a child-proof cap with a seal containing polyvinylidene chloride.

**6.6 Special precautions for disposal and other handling** No special requirements.

**7. Marketing authorisation holder**

Alben Health Care Industries Ltd., Onitsha Awka Road, Ogidi Anambra