NEW ZEALAND DATA SHEET

1. ALLERSOOTHE ELIXIR

Allersoothe 5 mg/5mL Elixir

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Allersoothe Elixir: Each 5 mL of the elixir contains 5 mg of promethazine hydrochloride.

Excipients with known effect:

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Elixir liquid.

Allersoothe Elixir is a clear, orange, syrupy liquid with banana and vanilla flavour. Each 5 mL of the elixir contains 5 mg of promethazine hydrochloride.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

1. Treatment of allergic conditions including some allergic reactions to drugs, urticaria and allergic contact dermatitis, and allergic reactions to insect bites and stings

2. Relief of excessive secretion in the upper respiratory tract as a result of hayfever and allergic rhinitis

3. Anti-emetic for vomiting from various causes including post-operative vomiting, irradiation sickness, drug induced nausea and motion sickness

4. Sedation - for short term use in adults under the advice of a doctor or pharmacist. Do not use for more than 7-10 consecutive days

5. Promethazine can be used as a pre-anaesthetic medication for the prevention and control of post-operative vomiting.

4.2 Dose and method of administration

Dose

Allersoothe should not be used in children less than two years of age. The dosage varies according to the condition being treated and the patient's response:

Allergic disorders

Children 2-5 years of age: 5-15 mg (5-15 mL) as a single dose at night or 5 mg (5 mL) 2-3 times daily.

Children 6-12 years of age: 10-25 mg (10-25 mL) as a single dose at night or 10 mg (10 mL) 2-3 times daily.

Children over 12 years and adults: 25-75 mg as a single dose at night or 10-20 mg 2-3 times daily.

Sedation

Give as a single dose at night.

Adults: 25-75 mg

Travel sickness

To be taken the night before travel and repeated after 6-8 hours on the following day if required.
Children 2-5 years of age: 5 mg (5 mL)

Children 6-12 years of age: 10 mg (10 mL)

Children over 12 years and adults: 25 mg

Nausea and vomiting

Children 2-5 years of age: 5 mg (5 mL) every 4-6 hours to a maximum daily dose of 15 mg (15 mL).

Children 6-12 years of age: 10 mg (10 mL) every 4-6 hours to a maximum daily dose of 20 mg (20 mL)

Children over 12 years and adults: 25 mg every 4-6 hours to a maximum daily dose of 100 mg.

4.3 Contraindications

• Patients with hypersensitivity to promethazine, substances with a similar chemical structure or to any of the excipients.

• Patients who are allergic to sodium benzoate.

• New born and premature infants

• Children under 2 years of age

• Women who are breast feeding

• Patients who have received high doses of other CNS depressants and/or are comatose

• Allersoothe should not be given for jaundice induced by other phenothiazine derivatives.

• Allersoothe should be avoided in patients who have been taking monoamine oxidase inhibitors within the previous 14 days.

4.4 Special warnings and precautions for use

Caution is advised in patients with:

• Cardiovascular disease

• Impaired hepatic function

• Impaired renal function or renal failure

• Acute or chronic respiratory impairment

• Epilepsy - epileptic patients may experience increased severity of convulsions

• Hypertensive crisis

• Narrow-angle glaucoma

• Stenosing peptic ulcer

• Symptomatic prostatic hypertrophy

• Bladder neck obstruction

• Pyloroduodenal obstruction

Those affected should not drive or operate machinery. Alcohol should be avoided.

Solar dermatitis has been reported following oral doses of promethazine in patients with eczema or a tendency to rheumatism.

QT interval prolongation has been reported with phenothiazines.

4.5 Interaction with other medicines and other forms of interaction

Promethazine may cause drowsiness and may enhance the sedative effects of CNS depressants e.g. alcohol, barbiturates, hypnotics, opiod analgesics, anxiolytic sedatives and neuroleptics and have additive anti-muscarinic actions with other anti-muscarinic drugs e.g. atropine and tricyclic antidepressants. Interactions between promethazine and monoamine oxidase inhibitors (MAOI) and tricyclic antidepressants may prolong and intensify the anticholinergic and CNS depressive effects.

Children

Children may experience paradoxical excitation. Use of promethazine in children and adolescents with sign and symptoms suggestive of Reyes syndrome should be avoided.

Promethazine should not be used in children under 2 years of age due to the potential for fatal respiratory depression.

Caution should be exercised when administering promethazine to children due to the potential for central and obstructive apnoea and reduced arousal. Excessive dosages may result in hallucinations, convulsions and sudden death.

Elderly patients

The elderly may experience paradoxical excitation.
The elderly are more likely to have CNS depressive side effects including confusion and are more susceptible to the anti-muscarinic effects of anti-histamines including hypotension

4.6 Fertility, pregnancy and lactation

Pregnancy and lactation

Category C

Promethazine has caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformations. These effects may be reversible. When promethazine has been given in high doses during late pregnancy, it has caused prolonged neurological disturbances in the infant. Promethazine should only be used during pregnancy if the potential benefits to the patient outweigh the potential risks to the foetus. Available evidence suggests that the amount excreted in breast milk is very low. However, there are risks of neonatal irritability and excitement. It should not be used unless the physician considers it essential.

4.7 Effects on ability to drive and use machines

Promethazine may cause drowsiness and may increase the effects of alcohol. Drowsiness may continue the following day. Those affected should not drive or operate machinery.

Patients receiving Allersoothe 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 reacting to the central nervous effects of the medicine and do not suffer from disorientation, confusion or dizziness

4.8 Undesirable effects

CNS Effects

CNS depressive effects of promethazine include sedation and impaired performance (impaired driving, poor work performance, incoordination, reduced motor skills and impaired information processing). Performance may be impaired in the absence of sedation and may persist the morning after a night-time dose. The stimulatory effects of promethazine may include anxiety, hallucinations, appetite stimulation, muscle dyskenesias and activation of epileptogenic foci. High doses of promethazine may cause nervousness, tremor, insomnia, agitation and irritability.

Anti-cholinergic Effects

Side effects of promethazine associated with cholinergic blockade include dryness of the eyes, nose and mouth, blurred vision, urinary hesitancy and retention, constipation and tachycardia.

Common Reactions

Gastrointestinal: Dry mouth, epigastric distress, loss of appetite, nausea, vomiting, constipation, diarrhoea

Nervous system: Sedation, restlessness, dizziness, lassitude, incoordination, fatigue

Ocular: Blurred vision

Less Common Reactions

Cardiovascular: Tachcardia, bradycardia, faintness

Dermatological: Contact dermatitis (topical), photosensitisation, urticaria, angioneurotic oedema, pruritus

Haematological: Leucopenia, agranulocytosis, aplastic anemia, thrombocytopenic purpura

Hepatic: Jaundice

Musculoskeletal: Extrapyramidal symptoms

Nervous system: Tinnitus, euphoria, nervousness, insomnia, convulsive seizures, oculogyric crises, excitation, catatonic-like states, hysteria, extrapyramidal symptoms, tardive dyskenesia

Respiratory: Marked irregular respiration Severe or Life-threatening Reactions Agranulocytosis, anaphylaxis. Allersoothe Elixir contains sodium benzoate which has been reported to cause hypersensitivity reactions.

Severe or life-threatening reactions

Agranulocytosis, anaphylaxis.
Allersoothe Elixir contains sodium benzoate which has been reported to cause hypersensitivity reactions.

4.9 Overdose

The main sign of acute poisoning from overdosage is unconsciousness which is commonly delayed. Convulsions, hallucinations, delirium, acute anxiety, psychotic reactions, extreme hyperaesthesia

and hyperalgesia with extensor plantar responses may also occur. Anti-cholinergic actions may cause tachycardia, flushed skin, dry mouth and sometimes mydriasis and urinary retention.

In adults CNS is more common with drowsiness, coma, convulsions, progressing to respiratory failure or cardiovascular collapse.

In infants and children, CNS stimulation predominates over CNS depression causing ataxia, excitement, tremors, psychoses, hallucinations, convulsions and possible hyperpyrexia which may be followed by deepening coma and cardiorespiratory collapse.

As with other phenothiazines symptomatic, supportive therapy is indicated. Maintenance of adequate ventilation should be instituted if necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Promethazine, a phenothiazine derivative, is a long acting antihistamine with mild atropine-like anticholinergic effects and some anti-serotonin effects. Because of its marked effect on the central nervous system (CNS), it acts as an anti-emetic, hypnotic, tranquiliser and a potentiator of anaesthetics, hypnotics, sedatives and analgesics. The antihistamine action has been reported to last for between 4 and 12 hours.

5.2 Pharmacokinetic properties

Promethazine is well absorbed after oral dosing with peak plasma concentrations being reached 2-3 hours after administration. Due to high first pass metabolism in the liver there is low systemic bioavailability after oral administration. It is widely distributed in the body, entering the brain and crossing the placenta. It is highly bound to plasma proteins (76-93%).
Promethazine undergoes extensive metabolism and is slowly excreted via urine and bile, mainly as metabolites. Elimination half-lives of 5-14 hours have been reported. Phenothiazines pass into breast milk at low concentrations.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colouring

Quinoline yellow, sunset yellow FCF.

Flavour

Banana flavour 10, vanillin

Other excipient

Citric acid, disodium edetate, glycerol, hyetellose, propyl gallate, propylene glycol, purified water q.s (to 1 mL), sodium citrate, sodium benzoate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months from date of manufacture stored at or below 25ºC.

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and contents of container

Bottles of 100 mL

6.6 Special precautions for disposal

No special requirements for disposal.

7. MEDICINE SCHEDULE

Pharmacist only medicine.

8. SPONSOR

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9. DATE OF FIRST APPROVAL

9 July 2009

10. DATE OF REVISION OF THE TEXT

21 September 2022

SUMMARY TABLE OF CHANGES

Date	Section(s) Changed	Change (s)
October 2020	4	Instructions for use in children for sedation removed
September 2022	4.1	Medsafe data sheet update request.

September 2022	4.5, 4.8	Correction of typographical errors and formatting.