Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

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Diphenhydramine Oral Solution BP 12.5 mg/5 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Diphenhydramine Hydrochloride BP 12.5 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral liquid

Light orange colored solution

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Symptomatic relief of

- perennial and seasonal allergic rhinitis,
- Vasomotor rhinitis and allergic conjunctivitis temporary relief of runny nose and sneezing caused by common cold.
- Dermatographism

4.2 Posology and Method of administration

Adults and Children over 12 years: 20ml (4 teaspoonfuls) at bedtime.

Children under 12 years: Not recommended.

Elderly: There is no need for dosage reduction.

Oral: route of administration

4.3 Contraindications

Hypersensitivity to any of the ingredients, liver disease, ventilatory failure and porphyria.

4.4 Special warnings and precautions for use

Children under 12 years should not be given this medicine.

Cough suppressants may cause sputum retention and this may be harmful in patients with chronic bronchitis and bronchiectasis.

This medicine should be used with care in conditions such as closed angle glaucoma, urinary retention, prostatic hypertrophy or pyloroduodenal obstruction. Caution should also be observed in patients with epilepsy and severe cardiovascular disorders.

4.5 Interaction with other medicinal products and other forms of interact.

CNS depressants: may enhance the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics and alcohol.

Antimuscarinic drugs: may have an additive antimuscarinic action with other drugs, such as atropine and some antidepressants.

MAOIs: not to be used in patients with MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome.

4.6 Fertility, Pregnancy and Lactation

The safety of Diphenhydramine in pregnancy has not been fully established but its use has not revealed any direct evidence of teratogenicity. However, in view of the possible association of foetal abnormalities with first trimester exposure to diphenhydramine, use of the product during pregnancy should be avoided. The safety of this product during lactation has not been established and use during this period should be avoided.

4.7 Effects on ability to drive and use machines

May cause drowsiness. If affected do not drive or operate machinery.

4.8 Undesirable effects

Common side-effects:

CNS effects: Drowsiness (usually diminishes within a few days), paradoxical stimulation, headache, psychomotor impairment.

Antimuscarinic effects: Urinary retention, dry mouth, blurred vision, gastrointestinal

disturbances, thickened respiratory tract secretions.

Rare side-effects: Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Symptoms

Symptoms of over dosage may include nausea, vomiting, drowsiness, restlessness excitement, ataxia, respiratory depression and occasionally convulsions and hyperpyrexia. In cases of severe overdosage, the stomach should be emptied by aspiration and lavage.

Treatment

If vomiting has not occurred spontaneously, the patient should be induced to vomit. This is best done by having him drink a glass of water or milk after which he should be made to gag. Precaution against aspiration must be taken, especially in infants and children.

If vomiting is unsuccessful, gastric lavage is indicated within 3 hours after ingestion and even later if large amounts of milk or cream were given beforehand. Isotonic or 1/2 isotonic saline is the lavage solution of choice.

Saline cathartics, as milk of magnesia, by osmosis draw water into the bowel and therefore are valuable for their action in rapid dilution of bowel content.

Stimulants should not be used.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Diphenhydramine has antihistamine properties with a pronounced sedative action.

5.2 Pharmacokinetic properties

Diphenhydramine undergoes extensive pre-systemic metabolism which results in 50% metabolism of an oral dose. The major route of elimination is in the urine, largely as metabolites with very little unchanged drug present.

5.3 Preclinical safety data

None stated.

6.0 Pharmaceutical particulars

6.1 List of excipients

Sucrose, Sodium Methylhydroxybenzoate, Sodium Methylhydroxybenzoate, Sodium benzoate, Disodium Edetate, Color sunset yellow supra, Citric acid monohydrate, Liquid Sorbitol (Non-Crystallising) BP, Mixed Fruit Flavour (Liquid) (In-House), Purified water.

6.2 Incompatibilities

None reported

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store at a temperature not exceeding 30^0C in a dry place.

6.5 Nature and contents of container

100 ml Amber colored Bottle

6.6 Special precautions for disposal and other handling

For oral use only

7. Marketing Authorisation Holder

MEDICAMEN BIOTECH LIMITED

SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan India

8. Number(s) in the national register of finished pharmaceutical products

Certificate No: 07970/08486/REN/2022

9. Date of first authorisation/renewal of the authorisation

Oct 21, 2022

10. Date of revision of the text

July 2023