SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Diphenhydramine Oral Solution BP 12.5 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Diphenhydramine hydrochloride BP 12.5 mg
Approved colour used

3. PHARMACEUTICAL FORM

Oral Solution
A clear red colour solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Diphenhydramine hydrochloride in the oral form is effective for the following indications:
Antihistaminic
For allergic conjunctivitis due to foods; mild, uncomplicated allergic skin manifestations of urticaria and angioedema; amelioration of allergic reactions to blood or plasma; dermatographism; as therapy for anaphylactic reactions adjunctive to epinephrine and other standard measures after the acute manifestations have been controlled.

Motion Sickness
For active and prophylactic treatment of motion sickness.

Antiparkinsonism
For parkinsonism (including drug-induced) in the elderly unable to tolerate more potent agents; mild cases of parkinsonism (including drug-induced) in other age groups; in other cases of parkinsonism (including drug-induced) in combination with centrally acting anticholinergic agents.

Nighttime Sleep-aid.

4.2 Posology and method of administration

DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT.

A single oral dose of diphenhydramine hydrochloride is quickly absorbed with maximum activity occurring in approximately one hour. The duration of activity following an average dose of diphenhydramine hydrochloride is from four to six hours.

Adults
25 to 50 mg three to four times daily. The nighttime sleep aid dosage is 50 mg at bedtime.

Pediatric Patients (over 20 lbs.)
12.5 to 25 mg three or four times daily. Maximum daily dosage not to exceed 300 mg. For physicians who wish to calculate the dose on the basis of body weight or surface area, the recommended dosage is 5 mg/kg/24 hours or 150 mg/m2/24 hours.

Data are not available on the use of diphenhydramine hydrochloride as a nighttime sleep-aid in children under 12 years.

The basis for determining the most effective dosage regimen will be the response of the patient to medication and the condition under treatment.

In motion sickness, full dosage is recommended for prophylactic use, the first dose to be given 30 minutes before exposure to motion and similar doses before meals and upon retiring for the duration of exposure

4.3 Contraindications

Use in Neonates or Premature Infants

This drug should not be used in neonates or premature infants.

Use in Nursing Mothers

Because of the higher risk of antihistamines for infants generally, and for neonates and prematures in particular, antihistamine therapy is contraindicated in nursing mothers.

Antihistamines are also contraindicated in the following conditions

Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

4.4 Special warnings and precautions for use

Warnings

Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction.

Use in Pediatric Patients

In pediatric patients, especially, antihistamines in overdosage may cause hallucinations, convulsions, or death. As in adults, antihistamines may diminish mental alertness in pediatric patients. In the young pediatric patient, particularly, they may produce excitation.

Use in the Elderly (approximately 60 years or older)

Antihistamines are most likely to cause dizziness, sedation, and hypotension in elderly patients.

Precautions

General

Diphenhydramine hydrochloride has an atropine-like action and therefore, should be used with caution in patients with a history of bronchial asthma, increased intraocular pressure, hyperthyroidism, cardiovascular disease or hypertension. Use with caution in patients with lower respiratory disease including asthma.

Information for Patients

Patients taking diphenhydramine hydrochloride should be advised that this drug may cause drowsiness and has an additive effect with alcohol. Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

Drug Interactions

Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals to determine mutagenic and carcinogenic potential have not been performed.

Pediatric Use

Diphenhydramine hydrochloride should not be used in neonates and premature infants.

Diphenhydramine hydrochloride may diminish mental alertness, or, in the young pediatric patient, cause excitation. Overdosage may cause hallucinations, convulsions, or death.

4.5 Interaction with other medicinal products and other forms of interaction

Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

4.6 Fertility, pregnancy and lactation

Carcinogenesis, Mutagenesis, Impairment of Fertility
Long-term studies in animals to determine mutagenic and carcinogenic potential have not been performed.
Pregnancy
Pregnancy Category B
Reproduction studies have been performed in rats and rabbits at doses up to 5 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to diphenhydramine hydrochloride. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

4.7 Effects on ability to drive and use machines

None Known

4.8 Undesirable effects

The most frequent adverse reactions are underscored.

1. General: Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of the mouth, nose and throat.
2. Cardiovascular System: Hypotension, headache, palpitations, tachycardia, extrasystoles.
3. Hematologic System: Hemolytic anemia, thrombocytopenia, agranulocytosis.
4. Nervous System: Sedation,sleepiness,dizziness,disturbedcoordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions.
5. GI System: Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
6. GU System: Urinary frequency, difficult urination, urinary retention, early menses.
7. Respiratory System: Thickening of bronchial secretions, tightness of chest or throat and wheezing, nasal stuffiness.

4.9 Overdose

Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in pediatric patients. Atropine-like signs and symptoms, dry mouth; fixed, dilated pupils; flushing and gastrointestinal symptoms may also occur.

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.
Vasopressors may be used to treat hypotension.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: Antihistamines for Systemic Use – aminoalkyl ethers
ATC code: R06AA02

Diphenhydramine is an ethanolamine-derivative antihistamine. It is an antihistamine with anticholinergic and marked sedative effects. It acts by inhibiting the effects on H1-receptors.
Diphenhydramine is effective in reducing sleep onset (i.e. time to fall asleep) and increasing the depth and quality of sleep.

5.2 Pharmacokinetic properties

Diphenhydramine hydrochloride is rapidly absorbed following oral administration.
Apparently it undergoes first-pass metabolism in the liver and only about 40-60% of an oral dose reaches systematic circulation as unchanged diphenhydramine.
It is rapidly distributed throughout the whole body. Peak plasma concentrations are attained within 1-4 hours. The sedative effect also appears to be maximal within 1-3 hours after administration of a single dose.
It is positively correlated with the plasma drug concentration.
Diphenhydramine is approx 80-85% bound to plasma proteins. Diphenhydramine is rapidly and almost completely metabolised. The drug is metabolised principally to diphenylmetoxyacetic acid and is also dealkylated.
The metabolites are conjugated with glycine and glutamine and excreted in urine.
Only about 1% of a single dose is excreted unchanged in urine.
The elimination half-life ranges from 2.4-9.3 hours in healthy adults. The terminal elimination half-life is prolonged in liver cirrhosis.

5.3 Preclinical safety data

Not known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Methyl Paraben, Sodium Propyl Paraben, Sorbic acid, Disodium EDTA, Citric acid, Sucralose, Colour Ponceou 4R, Flavour Rose White.

6.2 Incompatibilities

Not known

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container and special equipment for use, administration or implantation

125 ml Amber PET Bottle.

6.6 Special precautions for disposal and other handling

None.

7. MARKETING AUTHORISATION HOLDER

Ciron Drugs & Pharmaceuticals Pvt. Ltd.
C- 1101 /1102, Lotus Corporate Park, Graham Firth Steel Compound,
Jay Coach Junction, Western Express Highway, Goregaon (East)
Mumbai- 400 063, India.

8. MARKETING AUTHORISATION NUMBER(S)

08332/09666/NMR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03.01.2023

10. DATE OF REVISION OF THE TEXT

14/07/2023

11. Reference

https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=6fe6fe2d-4405-4e7a-a2ed-5eb367d52842#:~:text=Diphenhydramine%20hydrochloride%20is%20an%20antihistamine,the%20molecular%20formula%20C%20...&text=Each%205%20mL%20contains%2012.5,alcohol%2014%25%20for%20oral%20administration.