

Further information can be obtained from your doctor or pharmacist.

ROYCE®

Product holder / Manufactured by:
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ROYCE®

DIPHENDRY SYRUP (Diphenhydramine Hydrochloride)

Presentation:

A clear, dark brown coloured solution with a raspberry taste and menthol odour.

Each 5ml contains Diphenhydramine Hydrochloride 7mg and Ammonium Chloride 67.5mg.

Indication:

For the relief of cough and nasal congestion due to common cold, influenza, allergy or bronchitis.

Dosage and Administration:

Children 2 to 12 years: 1-2 teaspoonfuls (5-10ml) three or four times daily. Do not give to children under 2 years of age.

Pharmacological Information:

Diphenhydramine Hydrochloride is an antihistamine with anticholinergic (drying) and sedative side effects. Antihistamines appear to compete with histamine for cell receptor sites in effector cells.

Ammonium chloride – Act reflexly, irritating the gastric mucosa and so stimulating respiratory – tract secretions.

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 1-4hours. 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 approximately 80-85% bound to plasma proteins. Diphenhydramine is rapidly and almost completely metabolized. 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 single dose excreted unchanged in urine.

The elimination half-life ranges from 2.4-9.3hours in healthy adults. The terminal elimination half-life is prolonged in liver cirrhosis.

Contraindication:

Hypersensitivity to diphenhydramine or structurally related antihistamines, breast feeding, full term or premature neonates.

Warning and Precautions:

Drowsiness – Caution patients about driving or engaging in other activities requiring mental alertness, and about using alcohol or other CNS depressants (see DRUG INTERACTIONS).

Elderly patients – Dizziness, sedation and hypotension occur more frequently in patients over 60 years of age.

Special-risk patients – Use with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction and with caution in patients with increased intraocular pressure, hyperthyroidism, cardiovascular disease, hypertension or a history of asthma or other lower respiratory tract diseases.

Children – Antihistamines may produce excitation in young children.

Warning :

- i) Not to be used in children less than 2 years of age.
- ii) To be used with caution and on doctor's or pharmacist's advice in children 2 to 6 years of age.

Pregnancy and Lactation:

Pregnancy

Reproduction studies in rats and rabbits given up to 5 times the human dose have shown no evidence of impaired fertility or harm to the fetus; use during pregnancy only if clearly needed.

Lactation

Contraindicated for use in nursing mothers due to the increased risk of antihistaminic side effects in newborns and infants.

Interactions with Other Medicaments:

Alcohol, tranquilizers, sedative-hypnotics and CNS depressants – increase CNS depression. MAO inhibitors – increases anticholinergic effects.

Side Effects:

Cardiovascular – Hypotension, headache, palpitations, tachycardia, extrasystoles.

Hematological – hemolytic anemia, thrombocytopenia, agranulocytosis.

Central Nervous System – Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paraesthesia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions.

Ophthalmic – Blurred vision, diplopia.

Gastrointestinal – epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.

Genitourinary – Urinary frequency, difficult urination, urinary retention, early menses.

Respiratory – Thickening of bronchial secretions, tightness in the chest and wheezing, nasal stuffiness.

Dermatological – Urticaria, drug rash, photosensitivity.

Hypersensitivity – Anaphylactic shock.

Other – Dry mouth, nose and throat, chills, excessive perspiration.

Symptoms and Treatment of Overdose:

Varies from CNS Depression (drowsiness, sedation, diminished mental alertness, cardiovascular collapse) to CNS stimulation (insomnia, excitement, hallucinations, ataxia, incoordination, athetosis, tremors, convulsions) and may include dizziness, tinnitus, blurred vision, and hypotension; CNS stimulation, followed by postictal depression, and atropine like symptoms (dry mouth, fixed dilated pupils; fever, flushing, GI disturbances) are particularly likely in children.

If a patient is conscious, induce emesis with syrup of ipecac, even though vomiting may have occurred spontaneously. If vomiting is unsuccessful, or contraindicated, perform gastric lavage with isotonic or ½ isotonic saline solution. Remove any remaining drug in the stomach by installation of activated charcoal. Administer a saline cathartic to rapidly dilute bowel content. Treatment is symptomatic and supportive. If breathing is significantly impaired, maintain an adequate airway and provide mechanically assisted ventilation; do not use analeptics. Vasopressor (eg; norepinephrine) may be used for significant hypotension. Treat hyperpyrexia by sponging with tepid water or use of ice packs or hypothermal blanket. For seizures, administer a short-acting barbiturates, diazepam or paraldehyde.

Storage Condition:

Store in a dry place (below 30°C). Keep container tightly closed. Protect from light.

Pack Size:

Plastic bottles containing 60ml, 90ml, 100ml and 120ml.

Product Registration Number:

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