

COMPOSITION

Adryl ® Syrup: Each 5 ml syrup contains Diphenhydramine Hydrochloride BP 10 mg.

DESCRIPTION

Adryl ® is a preparation of Diphenhydramine Hydrochloride. It is a well absorbed antihistamine and widely distributed throughout the body, including the CNS. It is principally used as a potent antihistaminic, antitussive, antiemetic, antiparkinsonian agent.

INDICATIONS

Adryl ® (Diphenhydramine Hydrochloride) is indicated for the treatment of following: 1) Seasonal, perennial & vasomotor rhinitis, 2) urticaria, angioneurotic edema, anaphylaxis, 3) pruritus, 4) preanesthetic medication, emesis, motion sickness, 5) miscellaneous including meniere's diseases and parkinsonism, 6) cough & cold. Sometimes it may use as a night time sleep aid and for the short-term management of insomnia.

DOSAGE AND ADMINISTRATION

Adults & Children over 12 years of age:

Most allergic conditions are controlled with 25 to 50 mg i.e., (12.5 to 25 ml of syrup) 3 to 4 times a day.

Children 6 to 12 years of age: 10 mg i.e., (5 ml of syrup) 3 to 4 times a day.

Children 1 to 6 years of age: 5 mg i.e., (2.5 ml of syrup) 3 to 4 times a day.

The maximum daily dosage not to exceed 300 mg in adults and children.

In motion sickness:

Adult: 25 to 50 mg 3 to 4 times a day.

Children (above 9.1 kg): 12.5 to 25 mg 3 to 4 times a day (5mg/ kg/ 24 hours). Not to exceed 300 mg per day. 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.

In parkinsonism:

Adult: 25 to 50 mg 3 to 4 times a day

Children (above 9.1 kg): 12.5 to 25 mg 3 to 4 times a day (5mg/ kg/ 24 hours). Not to exceed 300 mg per day.

In insomnia:

Adults and children over 12 years of old: A dose of 20 to 50 mg is used as hypnotic in insomnia.

In cough & cold:

Adults: 25 mg every 4 hrs. Not to exceed 150 mg in 24 hours.

Children (6 to 12years): 12.5 mg every 4 hours. Not to exceed 75 mg in 24 hours.

Children (2 to 6 years): 6.25 mg every 4 hours. Not to exceed 25 mg in 24 hours.

CONTRAINDICATIONS

Diphenhydramine Hydrochloride is contraindicated for the premature or newborn infants. Any patients in whom drowsiness is undesirable e.g. drivers, machine operators. Concomitant consumption of alcohol or central nervous system (CNS) depressants will potentiate drowsiness. Patients with known hypersensitivity to Diphenhydramine or any components of the product.

PRECAUTIONS

Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined.

DRUG INTERACTIONS

Diphenhydramine hydrochloride administration significantly reduces the absorption of the antituberculous agent para-aminosalicylic acid (PAS) from the gastrointestinal tract. It has also additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

OVERDOSAGE

Antihistamine over dosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine like signs and symptoms such as dryness of mouth, fixed and dilated pupils, flushing and gastrointestinal symptoms may also occur.

SIDE EFFECTS

Side effects include drowsiness, dizziness, dryness of mouth, blurred vision, nausea and vomiting.

USE IN PREGNANCY & LACTATION

There are no adequate and well-controlled studies in pregnant women using diphenhydramine hydrochloride. Therefore, diphenhydramine hydrochloride should be used in pregnancy only if clearly needed. Diphenhydramine hydrochloride has been reported to be excreted in breast milk and thus, use of diphenhydramine hydrochloride in lactating mother is not recommended.

PHARMACEUTICAL PRECAUTION

Store at a cool and dry place, away from light. Keep out of the reach of children.

HOW SUPPLIED

Adryl ® Syrup: Each bottle contains 100 ml syrup and a measuring cup.