DIPHENHYDRAMINE HCl

RABAPHEN
50 mg/mL Solution for Injection (I.M./I.V.)
ANTICHOLINERGIC

℞

FORMULATION:
Each mL ampoule contains:
Diphenhydramine Hydrochloride, USP ..... 50 mg

PRODUCT DESCRIPTION:
Diphenhydramine Hydrochloride (Rabaphen) is available as clear, colorless, sterile, apyrogenic liquid.

INDICATIONS:
Diphenhydramine, a monoethanolamine derivative, is a sedating antihistamine with antimuscarinic and pronounced sedative properties. Itis used for the symptomatic relief of allergic conditions including urticaria and angioedema, rhinitis and conjunctivitis, and in pruritic skin disorders. Itis also used for its anti-emetic properties in the treatment of nausea and vomiting, particularly in the prevention and treatment of motion sickness (when it should be given at least 30 minutes before travelling), and in the treatment of vertigo of various cases. Diphenhydramine is used for its antimuscaritinic properties in the control of parkinsonism and drug-induced extrapyramidal disorders (although the possibility that Diphenhydramine itself may cause extrapyramidal symptoms should be remembered). Diphenhydramine has pronounced central sedative properties and may be used as a hypnotic in the short-term management ofinsomnia. Itis a common ingredient of compound preparations for symptomatic treatment of coughs and the common cold. It may also be given in combination preparations containing analgesics, particularly paracetamol. Diphenhydramine may be used parenterally as an adjunctin the emergency treatment of anaphylactic shock or when oral therapy is notfeasible.
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PHARMACOKINETICS:
Diphenhydramine hydrochloride is well absorbed from the gastrointestinal tract, although high first-pass metabolism appears to affect systemic availability. Peak plasma concentrations are achieved about 1 to 4 hours after oral doses. Diphenhydramine is widely distributed throughoutthe body including the CNS. It crosses the placenta and has been detected in breast milk. Diphenhydramine is highly bound to plasma proteins. Metabolism is extensive. Diphenhydramine is excreted mainly in the urine as metabolites; little is excreted as unchanged drug. The elimination half-life has been reported to range from 2.4 to 9.3 hours.

DOSAGE AND ADMINISTRATION:
For mostindications, Diphenhydramine hydrochloride is given by mouth in usual doses of 25 to 50 mg three or four times daily. The dose for children is 6.25 to 25 mg three or four times daily, or a total daily dose of 5 mg/kg may be given in divided doses. The maximum dose in adults and children is about 300 mg daily. A dose of 20 to 50 mg may be used as a hypnotic in adults and children over 12 years old. When oral therapy is notfeasible, Diphenhydramine hydrochloride may be given by deep intramuscular injection or by intravenous injection using concentrations of 1% or 5%. Usual doses are 10 to 50 mg, although doses of 100 mg have been given. No more than 400 mg should be given in 24 hours. Children may be given 5 mg/kg daily in divided doses to a maximum of 300 mg in 24 hours. Diphenhydramine hydrochloride is applied topically, usually in preparations containing 1 to 2% although, as with other antihistamines, there is a risk of sensitisation. Diphenhydramine citrate is given by mouth in a dose of 76 mg at nightin combination preparations for its hypnotic action. Diphenhydramine di(acefyllinate) is given by mouth as an antiemetic for the prevention and treatment of motion sickness and of nausea and vomiting; the usual dose is 90 to 135 mg. Other Diphenhydramine salts that have been used include the polistirex, the salicylate, and the tannate by mouth, the methylbromide rectally, and the metilsulfate applied topically. Dimenhydrinate is Diphenhydramine teoclate and mefenidramium metilsulfate is Diphenhydramine methylsulfomethylate.

CONTRAINDICATIONS:
Diphenhydramine is contraindicated in patients with hypersensitivity to the drug. It should not be administered to patients with asthmatic attack, pulmonary emphysema, dyspnoea by a chronic bronchitis, glaucoma, and low urinary obstruction including prostaticchypertrophy. It is also contraindicated in patients with stenoic peptic or pylorous duodenal obstruction, and chromaffinoma. Diphenhydramine is also contraindicated in patients with convulsive disease including epilepsy. It should not be administered to children under 12 years.

ADVERSE EFFECTS:
CNS depression, with effects varying from slight drowsiness to deep sleep and including lassitude, dizziness and incoordination, headache, psychomotor impairment and anti-muscarinic effects. Thickened respiratory tract secretions, blurred vision, urinary difficulty or retention constipation and increased gastric reflux.

REPORTING OF SUSPECTED ADVERSE DRUG REACTION:
To allow continued monitoring of the benefit/risk balance of the medicinal product, reporting of suspected adverse reaction is necessary. Healthcare professionals are encouraged to report any suspected adverse reactions directly to the importer/distributor at info@saharpharma.com and/or report to FDA: www.fda.gov.ph.
Patients are advised to seek immediate medical attention at the first sign/s of adverse reaction.

WARNINGS & PRECAUTIONS:
Special care should be given in administering Diphenhydramine to patients with severe myasthenia and to patients receiving MAO inhibitors. The drug should not be administered for a long time. If insomnia continues for 2 weeks or more after administration of this drug, counseling with a doctor is needed.
The performance of potentially hazardous tasks such as driving a car or operation of machinery is not recommended in patients receiving Diphenhydramine due to drowsiness.
They should also be used with care in condition such as angle closure glaucoma, urinary retention, prostatic hyperplasia, or pyloroduodenal obstruction. They are not intended to be used in neonates owing to their increased susceptibility to anti-muscarinic effects.

DRUG INTERACTIONS:
May enhance the sedative effects of CNS depress nts including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytics, sedatives and anti-psychotics.
They have an additive anti-muscarinic action with other anti-muscarinic drugs such as atropine and some anti-depressants (both tricyclic & MAOI's).

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE CONDITIONS:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
USP Type I Amber Glass Ampoule x 1 mL (Box of 10's)

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Manufactured by:
ZHEJIANG RUIXIN PHARMACEUTICAL CO., LTD.
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