

# Reals NIGHT AID Tablet

## Composition

Each film coated tablet contains:

Diphenhydramine HCL BP 50 mg

Excipients Q.S

Colour: Brilliant Blue Lake & Titanium Dioxide BP

## Pharmacodynamics

**Antihistamine action:** Antihistamines compete for H-receptor sites on the smooth muscle of the bronchi, GI tract, uterus and large blood vessel; by binding to cellular receptors, they prevent access of histamine and suppress histamine-induced allergic symptoms, even though they don't prevent its release.

**Antivertigo, antiemetic and antidyskinetic actions:** Central antimuscarinic actions of antihistamines probably are responsible for these effects of diphenhydramine.

**Antitussive action:** Drug suppresses the cough reflex by a direct effect on the cough center.

**Sedative action:** Mechanism of the CNS depressant effects of diphenhydramine is unknown.

**Anesthetic action:** Drug is structurally related to local anesthetics, which prevent initiation and transmission of nerve impulses, this the probable source of its tropical and local anesthetic effects.

## Pharmacokinetics

**Absorption:** Well absorbed from GI tract.

**Distribution:** Distributed widely throughout the body, including the CNS; The drug crosses the placental barrier and appears in breast milk. Drug is about 82% protein-bound.

**Metabolism:** About 50% to 60% of an oral dose of diphenhydramine is metabolized by the liver before reaching the systemic circulation (first-pass effect); virtually all available drug is metabolized by the liver within 24 to 48 hours.

**Excretion:** Plasma elimination half-life of drug is about 2 1/2 to 9 hours; drug and metabolites are excreted primarily in the urine.

Route	Onset	Peak	Duration
P.O	15-30 min	1-4 hr	4-8 hr
I.V	Immediate	1-4 hr	6-8 hr
I.M	Unknown	1-4 hr	6-8 hr
Topical	Unknown	Unknown	Unknown

### Indications and Usage:

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: treatment of urticaria and angioedema: amelioration allergic reactions to blood or plasma; adjunct to epinephrine and other standard measures in anaphylaxis: relief of uncomplicated allergic conditions of immediate type when oral therapy is impossible or contraindicated (parental form); treatment and prophylactic treatment of motion sickness ( injection only); nighttime sleep aid; management of parkinsonism ( including drug-induced) in elderly who are intolerant of more potent agents, in mild cases in other age groups and in combination with centrally acting anticholinergics; control of cough from colds or allergy ( syrup formulations).

**Dosage:** Adults and children over 16 years: 1 tablet at bedtime or as directed by physician

Not for use for children below 16 years

### Contraindications and precautions

Contraindicated in patients hypersensitive to drug, patients having acute

asthmatic attack and neonates, premature neonates and breast-feeding women. Use with extreme caution in patients with angle closure glaucoma prostatic hyperplasia, pyloroduodenal and bladder neck obstruction, COPD, increased intraocular pressure, hyperthyroidism, CV disease, hypertension

### Interactions

Drug-drug. CNS depressants such as anxiolytics, barbiturates, sleeping acids and tranquilizers. Causes additive CNS depression. Use together cautiously.

Heparin: Partially counteracts anticoagulant effects of heparin. Monitor PT and INR.

MAO inhibitors: Increases anticholinergic effects. Don't use together

Sulfonylureas: May diminish effects of sulfonylureas. Monitor patient closely.

Drug-lifestyle: Alcohol use may cause additive CNS depression Discourage alcohol use

Sun exposure: May cause photosensitivity reactions. Advise patient to take precautions.

## Adverse reactions

CNS: drowsiness confusion, insomnia, headache, vertigo, sedation, sleepiness, dizziness, incoordination, fatigue, restlessness tremor, nervousness, seizures.

CV: palpitations, hypotension, tachycardia.

EENT: diplopia blurred vision, tinnitus

GI: nausea, vomiting, diarrhea, dry mouth, constipation, epigastric distress, anorexia

GU: dysuria, urine, retention, urinary frequency.

Hematologic: hemolytic anemia, thrombocytopenia, agranulocytosis.

Respiratory: nasal congestion, thickening of bronchial secretions.

Skin: urticarial photosensitivity, rash; Other: anaphylaxis.

## **Overdose and treatment:**

Drowsiness is the usual symptom of overdose. Seizures, coma, and respiratory depression may occur with profound overdose. Anticholinergic symptoms, such as dry mouth, flushed skin, fixed and dilated pupils and GI symptoms are common especially in children. Treat overdose by including emesis with ipecac syrup (in conscious patient), followed by activated charcoal to reduce further drug absorption. Use gastric lavage if patient is unconscious or ipecac fails. Treat hypotension with vasopressors and control seizures with diazepam or phenytoin. Don't give stimulants.

## **Special considerations:**

Ask patient under-going skin testing for allergies about current drug therapy. stop drugs 4 days before diagnostic skin tests; antihistamines can prevent, reduce or mask positive skin test response.

**Breast-feeding patients:** Many antihistamines appear in breast milk. exposing the infants to risks of unusual excitability, premature infants are at particular risk for seizures. Avoid use of antihistamines during breast feeding.

**Pediatric patients:** Drugs shouldn't be used in premature infants or neonates. Infants and children, especially does younger than age 6, may experience paradoxical hyperexcitability.

**Geriatric patients:** These patients are usually more sensitive to adverse effects to antihistamines than younger patients and are especially likely to experience a greater degree of dizziness, sedation, hyperexcitability, dry mouth and urine retention. Symptoms usually respond to decrease in dosage.

**Patient education:** Advise patients that drowsiness is very common initially, but may be reduced with continue use of drug. Tell patients to take drug 30 mins before exposure to motion for motion sickness and before meals and bed time during exposure. Reactions may be common, uncommon, life-threatening or common and life threatening.

**Storage:** Store at a temperature below 30<sup>0</sup>C. Avoid excessive humidity.

**Presentation:** Reals Night Aid Tablets available 3x10 blister pack in a printed carton.