

Primera

DIPHENHYDRAMINE HYDROCHLORIDE

DIPLEX

12.5 mg / 5 mL Syrup
H₁-RECEPTOR ANTAGONIST
(ANTIHISTAMINE)

DESCRIPTION OF THE PRODUCT:

Diphenhydramine Hydrochloride (Diplex) 12.5 mg/5 mL is a clear orange syrup with tutti-frutti flavor and sweet fruit taste.

WHAT IS IN THE MEDICINE:

This product contains Diphenhydramine Hydrochloride, an antihistamine, which diminishes or abolishes the main actions of histamine in the body by competitive blockage of histamine receptor sites on tissues; does not inactivate histamine or prevent its synthesis or release. Histamine H₁ receptors are responsible for vasodilation, increased capillary permeability, flare and itch reactions in the skin, and to some extent for contraction of smooth muscle in the bronchi and gastrointestinal tract. A single oral dose of Diphenhydramine Hydrochloride (Diplex) is quickly absorbed, with maximum activity occurring in approximately one hour. The duration of activity following an average dose of Diphenhydramine Hydrochloride (Diplex) is 4 to 6 hours.

STRENGTH OF THE MEDICINE:

Each 5 mL (1 teaspoonful) of syrup contains:
Diphenhydramine Hydrochloride, USP.....12.5 mg

WHAT IS THIS MEDICINE USED FOR?

Used for the symptomatic relief of hypersensitivity reactions and for the control of nausea, vomiting and vertigo of various case.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Usual dose for pediatric: 6.25 mg to 25 mg three to four times a day, or a total daily dose of 5 mg/kg body weight in divided doses, up to maximum of 300 mg daily.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Diphenhydramine Hydrochloride (Diplex) is contraindicated in patients with hypersensitivity to Diphenhydramine Hydrochloride and other antihistamines of similar chemical structure; contraindicated to premature infants and newborn; should not be used by treating lower respiratory disease including asthma.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

May cause drowsiness; patients should not drive or operate machinery, Alcoholic drinks should also be avoided.

Pregnant patients should see their physician for a proper diagnosis and for treatment recommendations before taking medications. No adequate and well controlled studies in pregnant women. This drug should be used during pregnancy only if prescribed by the physician.

Use all forms of Diphenhydramine Hydrochloride with caution in breast-feeding women. Small, single or occasional doses of Diphenhydramine Hydrochloride, when necessary, would not be expected to cause adverse effects in breast-fed infants. However, large doses or prolonged use may cause adverse effects in the breast-fed infants or decrease the mother's milk supply, particularly when used in combination with sympathomimetic drugs or before lactation is well established.

UNDESIRABLE EFFECTS OF THIS MEDICINE:

Most common side effect is sedation. Paradoxical central nervous system stimulation may occur especially in children, with insomnia, nervousness, euphoria, irritability, tremors, and rarely, nightmares, hallucinations and convulsions may produce dry mouth; thickened respiratory tract secretions and tightness of the chest, blurred vision, urinary difficulty and retention; a reduction in tone and motility of the gastrointestinal tract resulting in constipation and increased gastric reflux; in high doses, transient bradycardia followed by tachycardia with palpitations and arrhythmias occurred.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

Diphenhydramine Hydrochloride (Diplex) may increase and potentiate effects with codeine, alcohol and other CNS depressants such as hypnotics, sedatives, tranquilizers. MAO inhibitors may prolong and intensify the anticholinergic effects of antihistamines. Diphenhydramine Hydrochloride (Diplex) contains anticholinergic properties and may result in tachycardia, dry mouth, headache and urinary tract retention.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose and the subsequent doses at the usual recommended schedule. Do not double dose unless directed by a physician.

SIGNS AND SYMPTOMS OF OVERDOSE

Anticholinergic signs and symptoms such as dry mouth, fixed and dilated pupils, flushing and gastrointestinal symptoms may occur. Overdosage of antihistamine may vary from central nervous system depression and stimulation particularly to pediatric patients. Treatment for overdose should be supportive and symptomatic. If vomiting has not occurred spontaneously, the patient should induce vomiting by drinking glass of milk or water, after which the patient should be made to gag. If vomiting is not successful, gastric lavage is indicated within 3 hours after ingestion. Isotonic saline is the lavage solution of choice. Precaution against must be taken, especially in pediatric patients. Vasopressor may be used to treat hypotension. Stimulants should not be used.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult your doctor immediately.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C.
Keep out of reach of children.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Consult your doctor if any undesirable effect occurs.

AVAILABILITY:

60mL Amber Bottle

ADR REPORTING STATEMENT:

For suspected adverse drug reaction, report to the FDA: www.fda.gov/ph
Seek medical attention immediately at the first sign of any adverse drug reaction.

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