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NUSSIDEX®

TABLETS.

Composition

Each tablet contains:

Active Ingredients

Dexchlorpheniramine maleate	1 mg
Pseudoephedrine (as hydrochloride)	25 mg

Other Ingredients
Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, talc, magnesium stearate, colloidal silicon dioxide, hydroxypropyl methylcellulose, titanium dioxide, polyethylene glycol 400.

Lactose content: 208 mg per tablet.
Sodium content: 0.31-0.47 mg per tablet.

Mechanism of Action

Dexchlorpheniramine is an alkylamine-type antihistamine. It is a highly active histamine antagonist, and is effective in relatively low doses.
Pseudoephedrine is a sympathomimetic which acts predominantly on α-receptors and has little effect on β-receptors. Therefore, it is an effective oral nasal decongestant with minimal CNS stimulation.
Since Nussidex is a preparation intended for the symptomatic treatment of allergic conditions, it has been formulated to exclude coloring agents. The possibility of sensitization reactions is thus minimized.

Indications

Symptomatic treatment of the common cold and allergic rhinitis (hay fever).

Contraindications

- Known hypersensitivity to either of the components of the preparation.
- Pregnant women in third trimester.
- Children under 6 years of age.
- Because of the antihistamine component, Nussidex is contraindicated in, closed-angle glaucoma , concomitant use with monoamine oxidase (MAO) inhibitor therapy, or within 14 days of stoping MAO inhibitor treatment (*also due to the pseudoepehdrine component*), concomitant use with sympathomimetic decongestants, beta blockers .
  Because of the pseudoephedrine component, Nussidex is contraindicated in severe hypertension and severe coronary artery disease, phaeochromocytoma, hyperthyroidism, diabetes mellitus, severe renal impairment.

Warnings

Use in Pregnancy
Use is contraindicated in third trimester.

Safety of use in pregnancy has not been established. Caution should be exercised when administered in 1st and 2nd trimesters .

Use in Breastfeeding
Caution should be exercised when administered in breastfeeding.

Use in the Elderly
The elderly may experience paradoxical excitation with dexchlorpheniramine maleate. In patients over 60 years of age, antihistamines may cause dizziness, sedation and hypotension. Also they are more likely to have central nervous system (CNS) depressive side effects, including confusion.

Adverse Reactions

Adverse reactions attributed to the antihistamine component (dexchlorpheniramine maleate)

Cardiovascular
Palpitations; tachycardia; extrasystoles; hypotension, hypertension.

Central Nervous System
Drowsiness; headache; sedation; dizziness; vertigo; disturbed coordination; fatigue; confusion; restlessness; excitation; nervousness; tremor; irritability; insomnia; euphoria; paresthesia; hysteria; neuritis; convulsions, depression, inability to concentrate, hyperreflexia, hyporeflexia, facial dyskinesia.

Dermatologic
Urticaria; drug rash.

Eye, Ear and Nose
Tinnitus; acute labyrinthitis; blurred vision; diplopia, dilated pupils, nasal stuffiness.

Gastrointestinal
Dryness of mouth (xerostomia) , nose, and throat; epigastric distress; anorexia; nausea; vomiting; diarrhea; appetite stimulation, constipation.

Genitourinary
Urinary frequency; difficult urination; urinary retention; early menstruation.

Hematologic
Hemolytic anemia; hypoplastic anemia; thrombocytopenia; agranulocytosis.

Respiratory
Thickening of bronchial secretions; tightness of chest; wheezing.

Miscellaneous
Anaphylactic shock; photosensitivity; excessive perspiration; chills.

Adverser Reactions attributed to pseudoepehdrine component
Cardiovascular stimulation – elevated blood pressure, tachycardia or arrhythmias.
Central nervous system (CNS) stimulation – restlessness, insomnia, anxiety, irritability, excitability, tremors and (rarely) hallucinations, skin rashes and urinary retention, cross-sensitivity with other sympathomimetics.

Other
Convulsions, hallucinations and paranoid delusion, nervousness, dizziness or lightheadedness, headache, increased sweating, nausea or vomiting unusual paleness, weakness,

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffect
Medic@moh.gov.il

Precautions

Since drowsiness may occur, patients should be cautioned against engaging in potentially hazardous activities requiring mental alertness, such as driving a car or operating machinery. The same precaution applies to childhood activities such as riding a bicycle or playing near traffic.
Patient should be warned not to drinl alcoholic beverages while under treatment with this medicine
Nussidex should be administered with caution to patients with a history of increased intraocular pressure, impaired function of the cardiovascular system (e.g. hypertension), kidney/urinary system, digestive system (e.g. ulcer, pyloroduodenal obstruction), nervous system (e.g. convulsions),
enlargement of the prostate gland, urinary bladder, neck obstruction or from peptic ulcer due to narrowing.
The elderly are more likely to exhibit adverse reactions: diziness, sedation, central nervous system depressive side effects (confusion) and hypotension.
Antihistamines may inhibit the cutaneous histamine response when performing skin tests using allergen extracts, thus producing false-negative results; it is therefore recommended that antihistamine-containing medication be discontinued at least 48 hours before testing begins.
Due to the antihistaminic component, this product should be used with caution in patients with liver disease.
Patients should be cautioned that the product may cause sensitivity to sunlight therefore they should avoid excessive exposure to the sun or UV light (eg, tanning booths) and to wear protective clothing and use sunscreens until tolerance is determined.
The preparation contains lactose, therefore patients who are sensitive to lactose should not use it.

Drug Interactions

Dexchlorpheniramine / Alcohol/CNS Depressants / Sedatives/Hypnotics / Opioid Analgesics / Tricyclic Antidepressants:
Concurrent use may potentiate the effects of either these medications or antihistamines.
Concomitant administration with tricyclic antidepressants may result in additive antimuscarinic activity

Nussidex/MAO Inhibitors: Concurrent use may prolong and intensify the anticholinergic effects of antihistamines and the effects of sympathomimetics. Severe hypertensive reactions may occur when sympathomimetics are administered to patients receiving MAO inhibitors, or within 14 days of stoping MAO inhibitor treatment. Concomitant use is therefore contraindicated (see Contraindications).

Antihistamines/Oral Anticoagulants: Action of oral anticoagulants may be decreased by antihistamines.
Pseudoephedrine/β-Blockers: β-Blockers increase the effects of sympathomimetics.
Pseudoephedrine/Methyldopa/Mecamylamine/Reserpine: The antihypertensive effects of these drugs may be reduced by sympathomimetics.
Pseudoephedrine/Inhalation Anesthetics: Administration of pseudoephedrine prior to or shortly after anesthesia may increase the risk of severe ventricular arrhythmias, especially in patients with pre-existing heart disease, because these anesthetics greatly sensitize the myocardium to the effects of sympathomimetics. Therefore caution is recommended in this situation.
Pseudoephedrine/Digitalis glycosides : Concurrent use with pseudoephedrine may increase the risk of cardiac arrhythmias; caution and electrocardiographic monitoring are very important if concurrent use is necessary.
Pseudoephedrine/Levodopa: Concurrent use with pseudoephedrine may increase the possibility of cardiac arrhythmias; dosage reduction of the sympathomimetic is recommended.
Pseudoephedrine//Sympathomimetics such as Decongestants, Appetite Suppressants and Amphetamine-like Psychostimulants): In addition to possibly increasing CNS stimulation, concurrent use may increase the cardiovascular effects of either the other sympathomimetics or pseudoephedrine.
Pseudoephedrine/Moclobemide: Risk of hypertensive crisis.
Pseudoephedrine/Ergot Alkaloids (Ergotamine and Methysergide): Increaed risk of ergotism.
Pseudoephedrine/Oxytocin:: Risk of hypertension.

Dosage and Administration

Adults
1-2 tablets, twice a day, after/with meals.

Children 6-12 Years of Age
1 tablet once a day ,after/with meals.

Overdosage

For Chlorpheniramine Maleate (Antihistamines)
Manifestations
Antihistamine overdosage reactions may vary from central nervous system depression to stimulation, especially in children. Atropine-like signs and symptoms such as dry mouth, fixed dilated pupils and flushing, as well as gastrointestinal symptoms, may occur.

Treatment
There is no specific therapy for acute overdosage with antihistamines. General symptomatic and supportive measures should be instituted promptly and maintained for as long as necessary.

Conscious Patients
Vomiting should be induced even though it may have occurred spontaneously. If the patient is unable to vomit, gastric lavage is indicated. Isotonic saline is the lavage of choice. Adequate precautions must be taken to protect against aspiration, especially in children.
Charcoal slurry or another suitable agent should be instilled into the stomach after vomiting or lavage. Saline cathartics or milk of magnesia may be of additional benefit.

Unconscious Patients
The airway should be secured with a cuffed endotracheal tube before attempting to evacuate the gastric contents. Intensive supportive and nursing care are indicated, as for any comatose patient.
Do not administer CNS stimulants.

Hypotension is an early sign of impending cardiovascular collapse. If a vasopressor agent is needed, noradrenaline, phenylephrine or dopamine is indicated. Use of adrenaline should be avoided since it may worsen hypertension. In case of convulsions, diazepam may be used and repeated as necessary.
When life-threatening CNS signs and symptoms are present, intravenous physostigmine salicylate may be considered.
Ice packs and cooling sponge baths, but not alcohol, can help in reducing the fever commonly observed in children.
Hemoperfusion may be used in severe cases.

For Pseudoephedrine
Manifestations
As with other sympathomimetic agents, symptoms of overdosage include: mild anxiety, irritability, restlessness, tremor, convulsions, palpitations, hypertension, and difficulty in micturition. Symptoms usually appear within 4-8 hours of ingestion and are transient, usually requiring no treatment.

Treatment
Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed if indicated. Catheterization of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

Registration Numbers
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Storage:
Store in a dry place, below 25°C.

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