PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed without a doctor's prescription

Nussidex®

Tablets

Composition

Each tablet contains:
Dexchlorpheniramine maleate 1 mg
Pseudoephedrine (as hydrochloride) 25 mg
For information regarding inactive ingredients and allergens, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if signs of the ailment (symptoms) worsen or do not improve.

1. WHAT IS THE MEDICINE INTENDED FOR?

For the symptomatic treatment of common cold and allergic rhinitis.

Therapeutic class

Dexchlorpheniramine maleate is an antihistamine of the polyamine class.

Pseudoephedrine hydrochloride is an alpha agonist, sympathomimetic decongestant.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredients or to any of the other ingredients this medicine contains (see details in section 6). Some of the symptoms of an allergic reaction may include: skin rash, breathing difficulties or fainting.
- The patient is a child under 6 years of age.
- You suffer from diabetes.
- You suffer from a tumor of the adrenal gland (pheochromocytoma).
- You suffer from an overactive thyroid gland.
- You suffer from severe kidney failure.
- You suffer from closed-angle glaucoma.
- You are being treated with medicines from the monoamine oxidase inhibitors group (MAOI) or within 14 days of discontinuing treatment with them.
- You are being treated with other decongestants (such as medicines for cough and common cold).
- You are being treated with beta blockers.
- You have very high blood pressure (severe hypertension) or hypertension that is not controlled by medicines, heart or vascular disease or a history of stroke.
- You have an acute (sudden) or chronic (long-term) kidney disease or kidney failure.

Special warnings regarding the use of the medicine
Before treatment with Nussidex, tell the doctor if:

- You are allergic to other medicines or food.
- You are pregnant, planning to become pregnant, breastfeeding or planning to breastfeed (see section "Pregnancy and breastfeeding").
- Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of medicines containing pseudoephedrine. PRES and RCVS are rare conditions that may involve reduced blood supply to the brain. Stop using Nussidex immediately and seek immediate medical assistance if you develop symptoms that may be signs of PRES or RCVS (see section 4 "Side effects" for the symptoms).
- You suffer or have suffered in the past:
  - From convulsions
  - From a kidney or liver disease
  - From an overactive thyroid
  - From a heart disease
  - From hypertension
  - From increased intraocular pressure
  - From prostate gland problems
  - From narrowing or blockage between the stomach and the small intestine which causes vomiting
  - From a peptic ulcer
  - From difficulty passing urine or from frequent urine passing, for example as a result of prostate gland problems or infection/inflammation of the bladder/urinary tract
  - From blockage of arteries or veins (obstructive vascular disease)
  - From a thyroid problem
  - From alcohol addiction

The medicine may cause dryness of the mouth, nose or throat. If the mouth dryness does not go away after two weeks, tell your doctor or dentist.

Effect on lab tests:

- Do not take this medicine 48 hours before allergy tests as this medicine may change the results of allergy tests.
- The medicine may cause a positive result in drug tests.

The elderly

Elderly patients may be sensitive to decongestant preparations. Using the medicine may cause dizziness, sedation, central nervous system depression effects (confusion) and low blood pressure.

Children and adolescents

Nussidex should not be used in children under 6 years of age.

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Alcohol
- Tricyclic antidepressants – used for treatment of mood disorders.
- Strong/narcotic painkillers (such as: codeine, morphine and dextropropoxyphene).
- Sleep medicines.
- Medicines for treatment of anxiety.
- Anticoagulant medicines (such as warfarin).
- Monoamine oxidase inhibitors (see above "Do not use the medicine if").
- Moclobemide – used for treatment of mood disorders.
- Anticholinergic medicines – used for treatment of cramps and spasms (such as atropine).
- Medicines for lowering blood pressure (such as: guanethidine, methyldopa, adrenergic neuron blockers, debrisoquine, bretylium, reserpine and bethanidine).
- Oxytocin (for inducing labor).
- Preparations that contain ergot alkaloids – used for treatment of migraine (such as: ergotamine and methysergide).
- Anesthetics.
- Stimulants or appetite suppressants and medicines used for treatment of congestion and asthma (sympathomimetic medicines).
- Cardiac medicines from the class of glycosides – used for controlling heart rhythm or contractions (such as digoxin).
- Metoclopramide or domperidone (for treatment of nausea and vomiting)
- Contraceptive pills
- Cholestyramine (for reduction of excess blood lipids)
- Anticonvulsants (medicines for treatment of epilepsy)

Use of the medicine and alcohol consumption

Do not drink alcohol during treatment with Nussidex.

The medicine may enhance the effect of alcohol and therefore drinking alcohol with the medicine may worsen the dizziness and drowsiness effects.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant, refer to the doctor or pharmacist for consultation before taking this medicine.

It is not recommended to use this medicine during pregnancy or breastfeeding, unless the potential benefit of the treatment to the mother outweighs the potential risks to the fetus or the breastfeeding infant.

Pregnancy

Dexchlorpheniramine maleate:

Safety during pregnancy has not been established.

During the first two trimesters of pregnancy, use the medicine only if there is a clear need.

It is recommended not to use it in the third trimester of pregnancy, as the fetus may have a severe reaction to antihistamines.

Dexchlorpheniramine maleate has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects on the fetus having been observed.

Pseudoephedrine hydrochloride:

Safety during pregnancy has not been established.

Based on the available data on pregnant women, it appears that no toxicity to the fetus or the newborn was observed.

Breastfeeding

Tell your doctor if you are breastfeeding or are planning to breastfeed.

Dexchlorpheniramine maleate – is excreted into breastmilk.

Pseudoephedrine hydrochloride – small amounts are excreted into breastmilk, however the effect on the breastfeeding infant is not known.

Fertility

There is no information regarding the effect of this product on fertility.

Driving and operating machinery

Use of this medicine may impair alertness and therefore caution should be exercised when driving a vehicle, operating dangerous machinery and during any activity which requires alertness. Children should be cautioned against riding a bicycle or playing near a road etc.

Sun exposure

This medicine may cause particular sensitivity upon exposure to the sun, therefore avoid exposure to the sun and ensure appropriate protection (long clothes, hat, sunscreens, etc.).

Important information about some of the ingredients of the medicine

Sodium – this medicine contains less than 1 mmol of sodium (23 mg) per tablet, and is therefore considered sodium-free.

Lactose – if you have been told by the doctor that you have an intolerance to sugars, consult the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

In the absence of any other instruction from the doctor, the usual dosage is:

Adults: 1-2 tablets, twice a day.

Children 6-12 years old: one tablet per day.

Do not exceed the recommended dose.

Method of use

The medicine should be taken with or after a meal.

No information is available regarding crushing/halving/chewing.

If you took an overdose or if a child accidentally swallowed this medicine, go immediately to a hospital emergency room and take the package of the medicine with you. Overdose symptoms include dizziness and breathing difficulties.

If you forgot to take this medicine at the required time, do not take a double dose. Take the next dose at the usual time and consult a doctor.

Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS

As with any medicine, using Nussidex may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

If you are above 60 years of age, you may be at increased risk of side effects.

Discontinue use and seek medical treatment or refer to a doctor immediately if any of the following effects occur:

- Chest pain.
- Sudden signs of an allergic reaction (such as: rash, blisters, itching and peeling of the skin).
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.
- Convulsions, fits or seizures.
- Coma.
- Sudden appearance of fever, redness in the skin, or many small pimples (possible symptoms of AGEP – Acute Generalised Exanthematous Pustulosis) – an effect that may occur during the first two days of treatment with this medicine.
- Sudden abdominal pain or rectal bleeding due to inflammation of the colon as a result of insufficient blood supply.
- Sudden appearance of severe headache, nausea, vomiting, confusion, irregular heart rhythm, visual disturbances.
- A decrease of blood flow to the heart that may cause angina pectoris (discomfort or pain in the chest, neck, back, jaw, shoulders, arms) or a heart attack.
- A stroke (weakness in the face, arms or legs or speaking problems).
- Problems passing urine (especially in men with prostate problems).
- Unusual tiredness, unexpected bruising or bleeding and contracting more infections (such as common cold) than usual.
- Sudden vision loss – decreased blood supply to the ocular nerve (ischemic optic neuropathy).
- Hallucinations, delusions or paranoia (hearing sounds and seeing visions that do not exist, thoughts and feelings that are not logical).
- If you develop symptoms that may be signs of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These symptoms include:
  - Sudden appearance of severe headache
  - Nausea
  - Vomiting
  - Confusion
  - Convulsions
  - Changes in vision

Very common side effects – effects that occur in more than one user out of ten

- Headache

Common side effects – effects that occur in 1-10 users out of 100

- Dry mouth or nausea
- Sleeping difficulties, nervousness or dizziness

Side effects with unknown frequency (effects whose frequency has not yet been determined)

- Anxiety, agitation, feeling of restlessness, irritability, feeling jittery or feeling of extreme happiness
- Sleep disturbances
- Fast or irregular heartbeat or increased awareness of your heartbeat (palpitations)
- Drowsiness
- High blood pressure
- Abdominal pain, diarrhea, vomiting
- Pain during urination
- Tingling (such as from pins and needles) or numbness in the hands or feet
- Tremors
- A decrease in blood flow to the optic nerve (ischemic optic neuropathy)
- Serious conditions that affect blood vessels in the brain known as posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS).

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects and drug interactions in children

Parents must report to the treating doctor all side effects and any additional medicine given to the child.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Keep this medicine in a dry place, below 25°C.

Do not discard medicines in wastewater or domestic trash. Ask your pharmacist how to discard medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredients, the medicine also contains:

Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, povidone, talc, magnesium stearate, colloidal silicon dioxide, hypromellose, titanium dioxide, macrogol/PEG 400.

What does the medicine look like and what are the contents of the package?

White, round, biconvex tablet.

Each package contains 20 or 30 tablets in a blister pack.

Not all package sizes may be marketed.

Name and address of the manufacturer and license holder:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

The leaflet was revised in March 2024.

Registration number of the medicine in the national drug registry of the Ministry of Health: 057-17-21688

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