



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

CADEX 1 MG, TABLETS / CADEX 2,4 MG, CAPLETS

Each **Cadex** 1 mg tablet contains doxazosin as mesylate 1 mg

Each **Cadex** 2 mg caplet contains doxazosin as mesylate 2 mg

Each **Cadex** 4 mg caplet contains doxazosin as mesylate 4 mg

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".

Read this entire leaflet carefully before you use this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their medical condition is similar.

1. What is the medicine intended for?

The medicine is intended for the treatment of hypertension and the treatment of benign prostatic hyperplasia.

Therapeutic group: Selective alpha-1 adrenoreceptor blockers.

2. Before using the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (doxazosin), to other types of quinazolines (such as prazosin or terazosin), or to any of the other ingredients this medicine contains (see section 6). This can manifest in itching, redness of the skin, or breathing difficulties.
- You suffer from benign prostatic hyperplasia and low blood pressure.
- You have a history of orthostatic hypotension, a type of low blood pressure that causes a feeling of dizziness when you stand up from sitting or lying down.
- You suffer from an enlarged prostate gland with one of the following conditions: any type of congestion or blockage of the urinary tract, a longstanding urinary tract infection, or bladder stones.
- You suffer from a certain type of incontinence due to bladder overflow (you do not feel the urge to urinate) or failure of the kidneys to produce urine (anuria) with or without kidney problems.

Special warnings regarding the use of the medicine

• Before treatment with Cadex, tell the doctor if:

- you are pregnant or trying to become pregnant
- you suffer from liver disease
- you are taking additional medicines
- you suffer from heart disease
- If you are about to undergo eye surgery because of cataract (cloudiness of the lens), inform the ophthalmologist before the surgery that you are taking or have previously taken **Cadex**, as **Cadex** may cause complications during the surgery which can be controlled if the doctor is prepared in advance.
- Before starting treatment with **Cadex**, your doctor may perform tests to rule out other conditions such as prostate cancer, which can cause the same symptoms as benign prostatic hyperplasia.
- Prolonged and painful erections may occur very rarely. In such a case, refer to the doctor immediately.

- At the beginning of treatment with **Cadex** you may feel faintness or dizziness due to low blood pressure when standing up from sitting or lying down. If you feel faint or dizzy you should sit or lie down until you feel better to prevent situations in which you might fall or be injured. Your doctor may wish to measure your blood pressure regularly at the beginning of treatment to reduce the possibility of these side effects occurring.

Children and adolescents

Cadex is not recommended for use in children and adolescents under 18 years of age, as the safety and efficacy of the medicine for use in children have not been established. Benign prostatic hyperplasia is not relevant to children.

Drug interactions

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

Some medicines may interact with **Cadex**. Ask your doctor or pharmacist before use if you are taking one or more of the following medicines as they may change the effect of **Cadex**:

- Some patients who take alpha blockers for the treatment of high blood pressure or prostatic enlargement may experience dizziness, which may be caused by low blood pressure when sitting or standing up quickly. Certain patients have experienced these symptoms when taking medicines called PDE5 inhibitors to treat erectile dysfunction (impotence) such as sildenafil, tadalafil, vardenafil with alpha blockers (see section "Special warnings regarding the use of the medicine"). To reduce the likelihood of these symptoms appearing, you should be on a regular daily dose with the alpha blocker before starting treatment for erectile dysfunction.
- **Cadex** may lower the blood pressure even more if you are taking other medicines to lower blood pressure.
- Medicines to treat bacterial or fungal infections such as clarithromycin, itraconazole, ketoconazole, telithromycin, voriconazole.
- Medicines for the treatment of HIV such as indinavir, nelfinavir, ritonavir, saquinavir.
- Nefazodone, a medicine to treat depression.

Use of the medicine and food

Cadex can be taken with or without food.

Pregnancy, breastfeeding and fertility

Pregnancy

The safety of using **Cadex** during pregnancy has not been established. If you are pregnant or are planning to become pregnant, consult the doctor or pharmacist before taking this medicine.

Breastfeeding

Small amounts of doxazosin, the active ingredient in **Cadex**, may be excreted in breast milk.

Do not use **Cadex** when breastfeeding except upon consultation with your doctor.

Driving and using machines

Take extra care if you drive or operate machinery. The medicine may affect your ability to drive or safely operate machinery, particularly at the beginning of the treatment. It may cause a feeling of weakness or dizziness. If affected, do not drive or operate machinery, refer immediately to the doctor.

Important information about some of the ingredients of the medicine.

This medicine contains lactose. If you have been told by the doctor that you have an intolerance to some sugars, consult the doctor before starting treatment with this medicine.

This medicine contains less than 1 mmol (23 mg) of sodium per tablet/caplet, that is to say essentially "sodium-free".

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine. The dosage and manner of treatment will be determined by the doctor only. The usual recommended dosage of **Cadex** is one tablet/ caplet once daily. If you are taking **Cadex** for the first time, the usual dosage is 1 mg daily. The doctor may increase the dosage after a couple of weeks to the usual dosage of 2 mg or 4 mg a day. In certain cases, the dosage may be increased to a maximum of 8 mg daily if you are being treated for benign prostatic hyperplasia or 16 mg if you are being treated for high blood pressure.

Do not exceed the recommended dose.

Cadex may be taken in the morning or in the evening. It is recommended to take the medicine with water at about the same time each day, with or without food. The tablet/caplet can be halved. There is no information about crushing or chewing. Do not wait until the package is finished before referring to the doctor.

Use in children

The safety and efficacy of using **Cadex** in children has not been established.

If you have accidentally taken a higher dosage

If you have accidentally taken a higher dosage, you may not feel well. Taking a number of tablets/caplets may be dangerous. If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, skip the forgotten dose. Then take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose. Continue with the treatment as recommended by the doctor. Even if there is an improvement in your health, do not change the dosage or stop the treatment with this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side Effects

Like any medicine, the use of **Cadex** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using Cadex and seek medical help immediately with the occurrence of one or more of the following effects:

- Heart attack
- Weakness of arms, legs, or problems speaking which may be symptoms of a stroke
- Swelling of the face, tongue or throat which may be a result of an allergic reaction to the medicine

Refer to a doctor immediately with the appearance of one or more of the following side effects after taking Cadex:

- Shortness of breath, breathing difficulties (common: a side effect that appears in 1-10 out of 100 users)

- Increased heartbeat (common: a side effect that appears in 1-10 out of 100 users)
- Feeling your heartbeat (palpitations) (common: a side effect that appears in 1-10 out of 100 users)
- Chest pain, angina (uncommon: a side effect that appears in 1-10 out of 1,000 users)
- Decreased heartbeat, irregular heartbeat (very rare: a side effect that appears in less than one out of 10,000 users)
- Yellowing of the skin or eyes (jaundice) (very rare: a side effect that appears in less than one user out of 10,000)
- Low white blood cell or platelets count which may result in frequent infections, hematomas (bruising), or easy bleeding (very rare: a side effect that appears in less than one user out of 10,000)
- Persistent painful penile erection. Seek urgent medical advice (very rare: a side effect that appears in less than one user out of 10,000)

Additional Side Effects:

Common side effects (effects that occur in 1-10 out of 100 users):

- Dizziness, feeling of spinning (vertigo), headache
- Low blood pressure
- Swelling of the feet, ankles, or fingers
- Bronchitis, coughing, respiratory tract (nose, throat, lungs) infection
- Nasal congestion, sneezing and/or runny nose caused by an inflammation of the lining of the nose (rhinitis)
- Abdominal pain, nausea
- Urinary tract infection, urinary incontinence, bladder inflammation
- Sleepiness, general weakness
- Indigestion, heartburn, dry mouth
- Itching
- Back pain, muscle pain
- Flu-like symptoms

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Constipation, gas, inflammation of the stomach and intestine (gastroenteritis) which may cause diarrhea and vomiting
- Pain or discomfort when urinating, increased frequency of urination, blood in the urine
- Joint inflammation (rheumatism), pain in the joints, general pain
- Facial swelling
- Insomnia, agitation, anxiety, depression or nervousness
- Reduced or altered sense of touch of the hands and feet
- Increased appetite or loss of appetite, weight gain
- Nosebleed
- Skin rash
- Ringing or noise in the ears, tremor
- Inability to achieve an erection
- An increase in liver enzymes, it may affect certain medical tests
- Stroke

Rare side effects (effects that occur in 1-10 users out of 10,000):

- Excessive urination
- Muscle cramps, muscle weakness

Very rare side effects (effects that occur in less than one user out of 10,000):

- Fainting or dizziness caused by low blood pressure when standing up from a sitting or lying position
- Hepatitis or biliary duct disorder
- Hives, hair loss, red or purple patches on the skin, bleeding under the skin

- A feeling of tingling or numbness of the hands and feet
- Tiredness, generally feeling unwell
- Wheezing
- Blurred vision
- Hot flushes
- Difficulty in urinating, an urge to urinate at night, increased volume of urine
- Discomfort or enlargement of the breasts in men

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- Ejaculation with no or little semen during sexual intercourse, cloudy urine following sexual intercourse
- Eye problems may occur during cataract (cloudiness of the lens of the eye) surgery. See section "Special warnings regarding the use of the medicine"

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

Side effects can be reported to the Ministry of Health via the link "דיווח על תופעת לוואי עקב" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the following link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional Information

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

Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, magnesium stearate, silica colloidal anhydrous, sodium laurilsulfate.

What the medicine looks like and what the package contains:

Cadex 1 mg: white to off-white colored tablets, round, biconvex, scored on one side.

Cadex 2 mg: white to off-white colored caplets, biconvex, scored on one side.

Cadex 4 mg: white to off-white colored caplets, biconvex, scored on both sides and "D4" embossed on one side.

Approved package sizes: 10, 28, 30, 90 tablets/ caplets. Not all package sizes may be marketed.

Revised in March 2020.

Drug registration number at the national drug registry of the Ministry of Health:

Cadex 1 mg: 113782960000

Cadex 2 mg: 113792960100

Cadex 4 mg: 113802960200

Manufacturer and registration holder:

Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel