

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) 1mg.

Each Cadex 2 mg caplet contains Doxazosin (as mesylate) 2mg.

Each Cadex 4 mg caplet contains Doxazosin (as mesylate) 4mg.

For list of excipients, see section 6 – "Additional information".

Read this entire leaflet carefully before you start using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same.

This medicine is not intended for children under 18 years of age.

1. What is the medicine used for?

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

Therapeutic group: selective alpha-1 adrenoceptor blockers.

2. Before you use the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (doxazosin), other types of quinazolines (such as prazosin or terazosin) or to any of the other ingredients of this medicine (listed in section 6). This can be manifested in itching, reddening of the skin or difficulty in breathing.
- You are breast-feeding.
- You are under 18 years of age.
- You suffer from an enlarged prostate gland (benign prostatic hyperplasia) and from low blood pressure.
- You have a history of orthostatic hypotension, a form of low blood pressure that causes you to feel dizzy when you stand up from sitting or lying down.
- You suffer from an enlarged prostate gland with one of the following: any kind of congestion or blockage in your urinary tract, a longstanding infection of the urinary tract or you have bladder stones.
- You suffer from overflow incontinence (you do not feel the urge to urinate), or anuria (your body is not producing any urine) with or without kidney problems.

Special warnings regarding the use of this medicine Before and during treatment with Cadex tell your doctor if:

- you are pregnant or trying to become pregnant
- you suffer from liver disease
- you are also taking other medicines

- you suffer from heart disease
- if you are about to undergo eye surgery because of cataract (cloudiness of the lens), please inform your eye specialist before the surgery that you are using or have previously used Cadex. This is because Cadex may cause complications during the surgery which can be managed if your doctor is prepared in advance.
- At the beginning of treatment with Cadex you may experience faintness or dizziness due to low blood pressure, when getting up from sitting or lying down. If you feel faint or dizzy, you should sit or lie down until you feel better and avoid situations where you might fall or get hurt. Your doctor may want to measure your blood pressure regularly at the beginning of therapy to reduce the possibility of these effects happening.

If you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements, please tell your doctor or pharmacist. Especially if you are taking:

- Some patients who take alpha-blockers for the treatment of high blood pressure or prostate enlargement may experience dizziness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking drugs for erectile dysfunction (impotence) with alpha-blockers. In order to reduce the possibility for these symptoms, you should be on a regular daily dose of your alpha blocker before starting treatment for erectile dysfunction.
- Cadex may lower your blood pressure even more if you are already taking other medicines to treat your high blood pressure such as terazosin and prazosin.

Use of the medicine and food

Cadex can be taken with or without food.

Pregnancy and breastfeeding

The safety of using Cadex during pregnancy has not been established. If you are pregnant or trying to become pregnant consult your doctor and he/she will decide if Cadex is suitable for you.

Do not take Cadex if you are breast-feeding.

Driving and use of machinery

Take extra care if you drive or operate machinery. The medicine may affect your ability to drive or operate machinery safely, particularly at the beginning of treatment. It may make you feel weak or dizzy. If affected, do not drive or operate machinery and refer to your doctor immediately.

Important information about some of the ingredients of this medicine

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

3. How to use this medicine

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure. The dosage and administration will be determined by the doctor only. The usual dose of Cadex is one tablet/caplet once daily.

If you are taking Cadex for the first time, the usual dose is 1mg daily. Your doctor may increase the dose after a couple of weeks to the usual dose of 2mg or 4mg daily. In certain cases this may be increased to a maximum of 8mg daily if you are being treated for prostate enlargement or to a maximum of 16mg if you are being treated for high blood pressure.

Do not exceed the recommended dose.

Cadex may be taken in the morning or the evening.

It is best to take your medicine at about the same time each day with a drink of water, with or without food. It may be halved. There is no information about crushing or chewing.

If you are not sure, ask your doctor or pharmacist.

Don't wait until your tablets are finished before seeing your doctor.

If you have accidentally taken a higher dosage

If you have accidentally taken a higher dosage you may feel unwell. Taking several 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 to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine

If you forget to take this medicine at the specified time, do not take a double dose.

Take the next dose at the regular time and consult your doctor. Continue with the treatment as recommended by your doctor. Even if there is improvement in your health, do not change the dosage or stop taking this medicine without consulting your doctor.

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

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

4. Side effects

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

STOP taking Cadex and seek immediate medical help if you experience any of the following:

- 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 the result of an allergic reaction to this medicine.

Tell your doctor immediately if you experience any of the following symptoms after taking Cadex:

- Chest pain, angina
- Shortness of breath, difficulty breathing
- Increased, decreased or irregular heartbeat
- Feeling your heartbeat (palpitations)
- Fainting
- Yellowing of the skin or the eyes (jaundice)
- Low numbers of white blood cells or blood platelets, which may result in frequent infections, bruising or easy bleeding
- Painful persistent erection of the penis

Additional side effects:

Common side effects (effects which appear in 1-10 users out of 100):

- Dizziness, feeling of spinning (vertigo), headache
- Low blood pressure
- Swelling of feet, ankles or fingers
- Bronchitis, coughing, respiratory tract (nose, throat, lungs) infection
- Nasal stuffiness, sneezing and/or runny nose caused by inflammation of the lining of the nose (rhinitis)
- Abdominal pain, feeling sick
- Urinary tract infection, urinary incontinence (inability to control passing urine), inflammation of bladder (cystitis)
- Sleepiness, general weakness
- Indigestion, heartburn, dry mouth
- Itching
- Back pain, painful muscles
- Flu-like symptoms

Uncommon side effects (effects which appear in 1-10 users out of 1,000):

- Constipation, wind, inflammation of the stomach and

intestines which can cause diarrhoea and vomiting

- Pain or discomfort on passing urine, increased frequency in passing urine, blood in urine
- Inflammation of the joints (gout), painful joints, general pain
- Swelling of the face
- Sleeplessness, agitation, anxiety, depression or nervousness
- Reduced or altered sense of touch of the hands and feet
- Increased appetite or loss of appetite, weight gain
- Nose bleed
- Skin rash
- Ringing or noise in the ears, tremor
- Inability to achieve penile erection
- An increase in liver enzymes which may have an effect on certain medical tests
- Stroke

Rare side effects (effects which appear in 1-10 users out of 10,000):

- Increased number of times of passing urine
- Muscle cramps, muscle weakness

Very Rare side effects (effects which appear in less than one user out of 10,000):

- Faintness or dizziness caused by low blood pressure when getting up from a sitting or lying position
- Hepatitis (liver inflammation) or bile disorder
- Hives, hair loss, red or purple patches on the skin, bleeding under the skin
- Tingling or numbness of the hands and feet
- Tiredness, generally feeling unwell
- Wheezing
- Blurred vision
- Hot flushes
- Disorder in passing urine, needing to pass urine at night, increased volume of urine passed
- Discomfort or enlargement of the breasts in men
- Painful persistent erection of the penis

Side effects with an unknown frequency (effects which their frequency has not been determined yet):

- Little or no semen ejaculated at sexual climax, cloudy urine following sexual climax
- Eye problems may occur during cataract (cloudiness of the lens of the eye) surgery. See section "special warnings regarding the use of this medicine".

If a side effect appears, if one of the side effects worsens or if you suffer from any side effect not listed in this leaflet, consult your doctor.

Side effects can be reported to the Ministry of Health by clicking on the link "דיוור על תופעות לוואי עקב טיפול תרופתי" that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse

events reporting or via the following link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. How to store the medicine

Avoid poisoning! This medicine, and any other medicine, should be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

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

Storing conditions: Do not store at temperature above 25°C.

6. Additional information

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

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

What the medicine looks like and contents of the package:

Cadex 1 mg: white to off-white, round, biconvex tablets, with a score-line on one side.

Cadex 2 mg: white to off-white, elongated, biconvex caplets, with a score-line on one side.

Cadex 4 mg: white to off-white, elongated, biconvex caplets, with a score-line on both sides and embossment "D4" on one side.

Approves pack sizes: 10, 28, 30, 90 tablets/caplets.

Not all pack sizes may be marketed.

This leaflet was checked and approved by the Ministry of Health on: 10/2016

Drug registration numbers at the national medicines registry of the Ministry of Health:

Cadex 1 mg: 113782960000

Cadex 2 mg: 113792960100

Cadex 4 mg: 113802960200

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Manufacturer and registration holder: **Dexcel® Ltd.**

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