**Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986**

This medicine is sold with a doctor's prescription only

# Adizem CD 120
# Adizem CD 180
# Adizem CD 240

**Controlled release capsules**

**Active ingredient:**
Each capsule of **Adizem CD 120** contains 120 mg diltiazem hydrochloride.
Each capsule of **Adizem CD 180** contains 180 mg diltiazem hydrochloride.
Each capsule of **Adizem CD 240** contains 240 mg diltiazem hydrochloride.

For a list of the other ingredients, please see section 6.
**Read this entire leaflet carefully before using the medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.
This medicine has been prescribed for treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

## 1. What is the medicine intended for?

The medicine is intended for the treatment of hypertension and angina.
**Therapeutic group**: Calcium channel blocker

## 2. Before using the medicine

**Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient, or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).
- You suffer from heart rhythm disorders (such as slow or irregular heartbeat).
- You suffer from heart failure.
- You are pregnant, planning to become pregnant or breastfeeding. See section 'Pregnancy and breastfeeding'.
- You are receiving concomitant dantrolene injections (a medicine used for treatment in cases of severe hyperthermia or severe muscle spasms).

**Special warnings regarding the use of this medicine:**

- Adizem capsules have a controlled release mechanism which enables the active ingredient to be gradually released over 24 hours.
  Do not chew or crush the capsule or its contents, since this may cause rapid release of the active ingredient (overdose) and severe problems. See section 'If you have accidently taken a higher dose'.
- Do not take damaged capsules.

- Use of this medicine should be reported before any medical procedure that includes general anesthesia.
- Elderly patients may be more sensitive to the effects of the medicine.
- If you are sensitive to any type of food or medicine, inform your doctor before taking this medicine.

**Before starting treatment, tell your doctor:**

- If you suffer or have suffered in the past from impaired function of the: heart and/or blood vessels, liver, kidney, gastrointestinal tract (intestinal problems).
- If you suffer from porphyria (a rare blood disease).

**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist**. Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using any of these medicines, please consult with your doctor or pharmacist):

- Dantrolene – do not use concomitantly with Adizem. See section ' Do not use this medicine if '.
- Other medicines for the treatment of high blood pressure, heart problems and/or blood vessels problems, such as: beta blockers (for example atenolol), diuretics, ACE inhibitors (for example captopril or enalapril); alpha blockers (for example prazosin, also used for the treatment of prostate disorders); ivabradine; cilostazol; antiarrythmics for the treatment of heart rhythm disorders for example amiodarone, digoxin, quinidine; nitrates (for example nitroglycerin).
- Medicines that may cause low blood pressure or slowing of the heart rhythm (for example antipsychotics for the treatment of mental problems or aldesleukin for the treatment of kidney cancer).
- Carbamazepine or phenytoin (for the treatment of epilepsy/seizures); benzodiazepines (medicines for sleeping or for the treatment of anxiety); medicines of the barbiturates group (for example phenobarbital); tricyclic anti-depressants (for example imipramine); lithium.
- Rifampicin (for the treatment of tuberculosis); protease inhibitors for the treatment of AIDS / HIV (for example ritonavir or atazanavir).
- Ciclosporine, sirolimus, tacrolimus (medicines to prevent the rejection of implants or for the treatment of immune system problems).
- Steroids (for example methylprednisolone).
- Statins to reduce the level of cholesterol in the blood (such as: simvastatin or atorvastatin).
- $H_2$ receptors antagonists for the treatment of stomach ulcers or heartburn (such as cimetidine or ranitidine).
- Theophylline (for the treatment of respiratory problems such as asthma).

**Use of the medicine and food:** this medicine may be taken regardless of meal times.
**Use of the medicine and alcohol consumption**: Do not drink wines or alcoholic beverages during the treatment period with this medicine.

**Driving and use of machinery:** The use of this medicine may cause side effects which

may affect your ability to drive or operate machinery, such as dizziness and general unwell feeling, or may impair alertness (see section 4, for the full list of side effects). These effects occur especially at the beginning of the treatment and/or when increasing the dosage. In the event that you feel effects which affect your ability to drive or operate machinery, do not perform these actions.

**Pregnancy and breastfeeding:**

- Do not use this medicine if you are pregnant or can become pregnant.
- Do not breastfeed during treatment with the medicine, since the medicine passes into breast milk.

**Use in children:** This medicine is not intended for children.

**Tests and follow-up:**
During the treatment period with this medicine, blood pressure tests and heart function tests: E.C.G. and heart rhythm, should be performed. A closer follow-up (especially after heart rhythm), is recommended at the beginning of the treatment in the elderly and in patients with kidney or liver insufficiency.

**3. How to use this medicine**
Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and manner of treatment.

**The dosage and the manner of treatment will be determined by the doctor only.**
This medicine is intended to be administered once daily (every 24 hours). Take the medicine at a set time.
**Do not exceed the recommended dose.**
Swallow the capsule whole with water. The medicine may be taken regardless of meal times. Do not chew or crush the capsule or its contents! See section 'Special warnings regarding the use of this medicine'.

**If you have accidentally taken a higher dose:** if you have taken an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or hospital emergency room and bring the package of the medicine with you.
Symptoms of an overdose may include: feeling unwell, feeling faint, slow heartbeat, loss of consciousness.

**If you forgot to take the medicine:**

- If you remembered within 4 hours from the time you were supposed to take the medicine, take the dose immediately. The next dose should be taken at the regular time.
- If you have delayed taking the medicine by more than 4 hours, consult with your doctor regarding the continuation of treatment.
- Never take two doses together!

Continue treatment as recommended by your doctor. Even if your state of health improves, do not stop treatment with the medicine without consulting your doctor.

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

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

**4. Side effects**
Like any medicine, the use of Adizem may 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.

**Refer to a doctor immediately in the following cases:**
**If symptoms of severe allergic reaction develop.** The symptoms may include: swelling of the face or throat; edema, shortness of breath; skin rash or itchiness, which may affect the whole body.
**If severe reactions of the skin occur** (such as Stevens-Johnson Syndrome, toxic epidermal necrolysis, erythema multiforme) which may include rash, red spots, blisters, flaking, or peeling. The reactions may be with or without fever.

**Additional side effects:**
*Very common side effects (appear in more than one user out of ten):*
Swelling (edema) in the extremities (hands, feet).
*Common side effects (appear in 1-10 users out of 100):*
Nausea, abdominal pain, indigestion, constipation; dizziness, headache; flushing and/or redness of the skin, itchiness; slow, rapid, strong or irregular heartbeat; generally feeling unwell, tiredness.
*Uncommon side effects (appear in 1-10 users out of 1,000)*:
Diarrhea, vomiting; feeling faint especially upon standing up; nervousness, sleep disturbances, impairment in liver function tests (seen in blood tests).
*Rare side effects (appear in 1-10 users out of 10,000):*
Dry mouth; hives (a skin reaction of rash and itchiness).
*Side effects of unknown frequency (effects whose frequency has not yet been determined):*
Heart failure which may cause shortness of breath and/or ankle swelling; inflammation of the liver, changes in muscle tone and/or disturbances in movement (extrapyramidal effects); mood changes including depression; skin problems such as allergic skin inflammation , increased sensitivity to light (including skin problems as a result of exposure to sun); reduction of blood platelets which increases the risk of bleeding and/or bruising (black and blue marks); breast enlargement in men; gum problems such as bleeding, tenderness, enlargement; inflammation of blood vessels (often accompanied by skin rash); excessive sweating; low blood pressure.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health

website (www.health.gov.il) which leads you to the online form for reporting side effects, or by entering the 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, must be stored in a safe 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 a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store in the original package below $25^{O}$C.

**6. Additional information**

- **In addition to the active ingredient, the capsules also contain:**
  Microcrystalline cellulose, ethylcellulose, colloidal anhydrous silica, polysorbate 80, dibutyl sebacate, erythrosine, indigo carmine, magnesium stearate, gelatin.

  Adizem CD 120 contains additionally quinoline yellow.

- **What does the medicine look like and what does the package contain?**
  Capsules containing off-white colored granules
  Capsule colors: Adizem CD 120 – yellow/red; Adizem CD180 – blue/red;
  Adizem CD 240 – purple/red.
  The capsules are packed in blisters, 30 capsules in a box.
- **Registration holder:** Rafa Laboratories Ltd., P.O.Box 405, Jerusalem 9100301.
- **Drug registration number in the National Drug Registry of the Ministry of Health:**
  Adizem CD 120: 1029527680
  Adizem CD 180: 1029627681
  Adizem CD 240: 1029727682

This leaflet was checked and approved by the Ministry of Health in October 2011 and was updated according to the guidelines of the Ministry of Health in January 2018.

I-301008