

## Package Leaflet: Information for the user

**Adizem<sup>®</sup>-SR 90 mg, 120 mg and 180 mg prolonged-release capsules, hard**  
Diltiazem hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet:

1. What **Adizem-SR** capsules are and what they are used for
2. What you need to know before you take **Adizem-SR** capsules
3. How to take **Adizem-SR** capsules
4. Possible side effects
5. How to store **Adizem-SR** capsules
6. Contents of the pack and other information

### 1. What **Adizem-SR** capsules are and what they are used for

These capsules have been prescribed for you to treat angina (chest pain caused by a reduction of oxygen to the heart muscle) or high blood pressure (hypertension). They contain the active ingredient diltiazem. Diltiazem belongs to a group of medicines called calcium antagonists. Calcium antagonists help more blood to reach the heart and reduce blood pressure. The other ingredients of **Adizem-SR** capsules are listed in section 6 of this leaflet.

**Adizem-SR capsules are designed to work properly over 12 hours. If the capsules are crushed or chewed, the entire 12 hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose.**

### 2. What you need to know before you take **Adizem-SR** capsules

#### Do not take **Adizem-SR** capsules if you:

- are allergic to diltiazem or any of the other ingredients of the capsules (see section 6 ‘Further Information’);
- have a slow or irregular heart beat;
- have heart failure (which can cause shortness of breath or ankle swelling);
- have heart problems other than angina and hypertension;
- are pregnant, might become pregnant or think you might be pregnant.
- are breastfeeding;
- are taking dantrolene (a muscle relaxant).

Children should not take these capsules.

### Warnings and precautions

Talk to your doctor or pharmacist before taking these capsules if you:

- have liver or kidney problems or are elderly, as your doctor may monitor you more closely, particularly when you start taking your capsules;
- have porphyria (a rare disease of the blood pigments);
- have diabetes as your medication may need to be adjusted;
- have bowel problems

In some patients, this medicine has caused mood changes including depression. If you think you are affected in this way, tell your doctor.

### **Other medicines and Adizem-SR capsules**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. If you take *Adizem-SR* capsules with some other medicines, the effect of *Adizem-SR* capsules or the other medicine may be changed.

Tell your doctor or pharmacist if you are taking:

- any other medicines for high blood pressure, such as beta blockers (for example atenolol), diuretics (for example bendrofluazide) or ACE inhibitors (examples include captopril and enalapril);
- medicines known as alpha blockers, which you may be taking to treat high blood pressure or prostate disorders (for example prazosin);
- any medicines which may cause low blood pressure or slow heart beat (for example aldesleukin to treat cancer of the kidneys, or antipsychotics to treat mental and behavioural disorders);
- ivabradine to treat angina;
- anti-arrhythmic medicines to treat an irregular or rapid heart beat (for example digoxin, amiodarone or beta-blockers);
- cilostazol to treat intermittent claudication (a condition that causes leg pain due to a restriction in blood to the muscles);
- medicines known as statins to reduce cholesterol levels in your blood (examples include simvastatin, atorvastatin or lovastatin);
- medicines known as H2 antagonists to treat stomach ulcers, indigestion or heartburn, such as cimetidine or ranitidine;
- carbamazepine or phenytoin to treat seizures, fits or convulsions;
- medicines known as benzodiazepines to treat anxiety or help you sleep (examples include midazolam or triazolam);
- medicines known as barbiturates to either treat fits or to help you sleep (examples include phenobarbital or primidone);
- antidepressants known as tricyclic antidepressants (e.g. amitriptyline or imipramine) or lithium;
- rifampicin to treat tuberculosis;
- ciclosporin, sirolimus or tacrolimus to prevent organ transplant rejection or treat other immune system disorders;
- a specific type of medicine known as protease inhibitors to treat HIV (examples include atazanavir or ritonavir);
- dantolene (a muscle relaxant);
- theophylline to treat breathing problems such as asthma;
- medicines known as nitrate derivatives to treat angina or high blood pressure (examples include glyceryl trinitrate or isosorbide mononitrate);
- medicines for inflammation or allergies, known as steroids (for example methylprednisolone).

### **Anaesthetics and Adizem-SR capsules**

If you are having a general anaesthetic, tell your doctor that you are taking these capsules.

### **Adizem-SR capsules with food, drink and alcohol**

Do not take these capsules at the same time as an alcoholic drink.

### **Pregnancy, breastfeeding and fertility**

Do not take these capsules if you are pregnant, likely to become pregnant or are breastfeeding.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

These capsules may cause a number of side effects such as dizziness and a general feeling of being unwell. These could affect your ability to drive or use machinery (see section 4 for a full list of side effects) and are usually most noticeable when you first start taking the capsules, or when changing to a higher dose. If you are affected you should not drive or use machinery.

### ***Adizem-SR* capsules contain sucrose**

These capsules contain sucrose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these capsules.

### **3. How to take *Adizem-SR* capsules**

Always take *Adizem-SR* capsules exactly as your doctor has told you. The label on your medicine will tell you how many capsules to take and how often.

#### **Adults (over 18 years of age)**

The usual starting dose is one 90 mg capsule twice daily. However, if you are elderly then you may need to start on a lower dose. Your doctor will decide how many capsules you should take.

#### **Children**

Children should not take these capsules.

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

Swallow your capsules whole with a glass of water. **Do not chew or crush the capsules.**

You should take your capsules every 12 hours. For instance, if you take a capsule at 8 o'clock in the morning, you should take your next capsule at 8 o'clock in the evening.

#### **If you take more *Adizem-SR* capsules than you should or if someone accidentally swallows your capsules**

Call your doctor or hospital straight away. People who have taken an overdose may become very unwell, feel faint, have a slow heart beat and lose consciousness. They may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show to the doctor.

#### **If you forget to take *Adizem-SR* capsules**

If you remember within 4 hours of the time your capsule was due, take your capsule straight away. Take your next capsule at your normal time. If you are more than 4 hours late, please call your doctor or pharmacist for advice. Do not take a double dose to make up for a forgotten capsule.

#### **If you stop taking *Adizem-SR* capsules**

You should not stop taking these capsules unless your doctor tells you to. If you want to stop taking your capsules, discuss this with your doctor first.

If you have any further questions on the use of *Adizem-SR* capsules, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, these capsules can cause side effects, although not everybody gets them.

Look out for the following severe allergic reactions. They have occurred in a small number of people, although their exact frequency cannot be estimated:

- swelling of the face or throat;
- skin rash or itching especially those covering your whole body, severe flaking, blistering or peeling of the skin, with or without a fever.

Tell your doctor immediately if you get any of these.

**Very common side effects** (May affect more than 1 in 10 people)

- Swelling of the hands, ankles or feet.

**Common side effects** (May affect more than 1 in 100 people)

- Feeling sick, abdominal pain, indigestion, constipation.
- Dizziness, headache.
- Flushing or redness of the skin, itching.
- A fast, slow or irregular heartbeat.
- Generally feeling unwell.
- Tiredness.

**Uncommon side effects** (May affect up to 1 in 100 people)

- Diarrhoea, being sick.
- A feeling of faintness, especially on standing up.
- Nervousness.
- Difficulty in sleeping.
- A worsening in liver function tests (seen in a blood test).

**Rare side effects** (May affect up to 1 in 1,000 people)

- Dry mouth.
- Hives.

**Frequency not known (Frequency cannot be estimated from the available data)**

- Heart failure which can cause shortness of breath or ankle swelling.
- Inflammation of the liver.
- Changes in muscle tone and/or abnormalities of movement.
- Mood changes, including depression.
- Skin problems such as increased sensitivity to sunlight.
- A reduction in blood platelets which increases the risk of bleeding or bruising.
- Breast enlargement in men.
- Bleeding, tender or enlarged gums.
- Inflammation of blood vessels (often with skin rash).
- Sweating.
- Low blood pressure.
- Loss of appetite

You may see the remains of the capsules in your faeces. This should not affect how the capsules work.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
IRL – Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store *Adizem-SR* capsules

Keep out of the sight and reach of children.

Do not use any capsules after the expiry date which is stated on the carton. EXP 08 2020 means that you should not take the capsules after the last day of that month i.e. August 2020.

Do not store your capsules above 25°C.

Do not take your capsules if they are broken or crushed as this can be dangerous and can cause serious problems such as overdose.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What *Adizem-SR* capsules contain

The active ingredient is diltiazem hydrochloride. Each capsule contains 90 mg, 120 mg or 180 mg of diltiazem hydrochloride.

The other ingredients are:

- Sucrose
- Maize starch
- Povidone
- Ethylcellulose
- Dibutyl sebacate
- Talc
- Sodium laurilsulfate
- Cetyl alcohol
- Gelatin
- Titanium dioxide (E171)
- Iron oxide (E172)

The 120 mg capsules also contain Indigo carmine (E132)

### What *Adizem-SR* capsules look like and the contents of the pack

*Adizem-SR* capsules are marked with the strength (e.g. 90 mg, 120 mg etc) and are coloured as follows: 90 mg – white, 120 mg - white/brown, 180 mg – white/pale brown.

The capsules are packed in blister packs and then placed in boxes. In each box there are 56 capsules.

### Marketing Authorisation Holder

Mundipharma Pharmaceuticals Ltd., Millbank House, Arkle Road, Sandyford, Dublin 18, Ireland.

### Manufacturer

Mundipharma DC B.V., Leusderend 16, 3832 RC Leusden, Netherlands.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information Line on:

**0044 1733 37 53 70**

You will need to give details of the product name and reference number.

These are as follows:

Product name: Adizem-SR prolonged release capsules

Reference number: 1688/1/1

**This leaflet was last revised in March 2019**

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