Package Leaflet: Information for the user

***Adizem*®*-SR* 90 mg, 120 mg and 180 mg prolonged-release capsules**
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 of the 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

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 (hypersensitive) to diltiazem or any of the other ingredients of the capsules (see section 6 'Further Information');
- have a very slow (less than 40 beats per minute) or irregular heart beat;
- have heart failure (which can cause shortness of breath or ankle swelling) and problems with blood flow to the lungs;
- 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)
- are already taking a medicine called lomitapide used for the treatment of high cholesterol levels (see section: 'Other medicines and Adizem-SR capsules).

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;
- have a history of heart failure, new shortness of breath, slow heartbeat or low blood pressure. As cases of kidney injury in patients with such conditions have been reported, your doctor may need to monitor your kidney function.

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.

In particular, do not take this medicine and tell your doctor if you are taking:

- Medicines containing lomitapide used for the treatment of high cholesterol levels. Diltiazem may increase the concentration of the lomitapide that may lead to an increase in the likelihood and severity of liver related side effects.

Tell your doctor or pharmacist if you are taking:

- any other medicines for high blood pressure, such as beta blockers (for example atenolol), diurectics (for example bendroflumethiazide) or ACE inhibitors (e.g. 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 a condition that causes leg pain due to a restriction in blood to the muscles, known as intermittent claudication;
- medicines known as statins to reduce cholesterol levels in your blood (examples include simvastatin or atorvastatin);
- medicines known as H_2 antagonists used to treat stomach ulcers, indigestion or heartburn, such as ranitidine;
- carbamezepine 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);
- antidepressents 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);
- dantrolene (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).
- Diltiazem may lead to increased risk of bleeding if taken along with blood thinners known as direct acting oral anti-coagulants (example apixaban, rivaroxaban, dabigatran).

Anaesthetics and *Adizem-SR* capsules
If you are having a general anaesthetic, tell your doctor that you are taking these capsules as some of the effects of the anaesthetic may be increased by these capsules.

Taking *Adizem-SR* capsules with 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.

***Adizem-SR* capsules contain sodium**
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

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.**
***Adizem*-SR capsules are designed to work properly over 12 hours when swallowed whole. If a capsule is broken, crushed, dissolved 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.**

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 immediately. People who have taken an overdose may become very unwell and the following effects may happen: feel faint, have a slow heartbeat, decrease of kidney function 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 reactions. They have occurred in a small number of people, although their exact frequency cannot be estimated:
- Allergic (hypersensitivity) reactions including 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 (known as Stevens-Johnson syndrome). 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 up to 1 in 10 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 (seen in a blood test).

Rare side effects (May affect up to 1 in 1000 people)
- Dry mouth.
- A raised, itchy rash (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.
- A condition in which the body's defence system attacks normal tissue causing symptoms such as swollen joints, tiredness and rashes (called 'lupus-like syndrome').

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
Website: www.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 blister and carton after EXP. The expiry date refers to the last day of that month.

Do not store your capsules above 25 °C.

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 capsules also contain the following colourants:
120 mg – 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., United Drug House Magna Drive, Magna Business Park, Citywest Road, Dublin 24, 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

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