PACKAGE LEAFLET: INFORMATION FOR THE USER

DILZEM SR 60 mg, 90 mg, 120 mg
Prolonged-release Hard 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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What DILZEM SR is and what it is used for

DILZEM SR contains the active ingredient, diltiazem hydrochloride.

Diltiazem belongs to a group of medicines called calcium channel blockers. These medicines work to lower blood pressure and ease anginal chest pain by preventing the narrowing of blood vessels.

DILZEM SR is used to treat and control **mild to moderately high blood pressure** and to prevent and treat **chest pain** due to the narrowing of blood vessels in the heart. DILZEM SR is designed to release the active ingredient, diltiazem, in a controlled manner throughout the whole day so that blood pressure and angina are treated for a full 24 hour period.

2. What you need to know before you take DILZEM SR

Do not take DILZEM SR if you:
- are allergic to diltiazem hydrochloride or any of the other ingredients of this medicine (see section 6)
- are a woman of a child-bearing potential and are not using contraception (see "Pregnancy, breast-feeding and fertility")
- are pregnant, think you may be pregnant or are breast-feeding (see "Pregnancy, breast-feeding and fertility")
- are currently in shock (reduced blood flow to vital organs)
- suffer from any serious heart problems such as heart failure with shortness of breath and abnormal heart rhythm, which may result in palpitation. You may need to have your heart rate monitored at the beginning of the treatment.
- have a very low pulse rate or low blood pressure
- are currently receiving an infusion of a muscle relaxant called dantrolene (this is only given in hospitals)
- are currently taking ivabradine, as taking it together with DILZEM SR may lower your heart rate (see section "Other medicines and DILZEM SR").

Warnings and precautions
Talk to your doctor or pharmacist before taking DILZEM SR if you:
- have diabetes
- have any liver or kidney problems or if you are 65 or over. You may need to have your heart rate monitored at the beginning of the treatment.
- have any heart problems, such as heart failure with shortness of breath, low pulse rate, abnormal heart rhythm which may result in palpitation
- have a rare disease of the blood pigment called "porphyria", or anyone in your family has it
- have myasthenia gravis (a nervous condition which causes muscle weakness)
- suffer from constipation
- are due to have surgery or visit your dentist (see "Other medicines and DILZEM SR").

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

If any of the above applies to you, please tell your doctor or pharmacist before taking DILZEM SR.

Children
DILZEM SR is NOT recommended for use in children.

Other medicines and DILZEM SR
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take this medicine and talk to your doctor or pharmacist if you are currently receiving an infusion of a muscle relaxant called dantrolene (this is only given in hospitals).

Also, **tell your doctor or pharmacist** if you are taking any of the following medicines:
- simvastatin, or atorvastatin (used to treat high cholesterol)
- lithium (used to treat mental problems)
- warfarin (used to thin the blood)
- nitrate derivatives (usually used to treat angina, such as glyceryl trinitrate, isosorbide dinitrate)
- theophilline (used to treat asthma)
- alpha-blockers (such as hytrin and doxazosin)
- any medicine used to treat heart problems, including beta-blockers (such as propranolol), amiodarone or digoxin
- methyldopa, nifedipine, diuretics (such as bendrofluazide), ACE inhibitors (such as enalapril), or

any other medicines used to treat high blood pressure
- phenobarbital or carbamazepine (used to treat epilepsy) or rifampicin (used to treat tuberculosis)
- cimetidine or ranitidine (medicines used to treat stomach problems)
- ciclosporin (which works by suppressing the body's immune or defence system)
- benzodiazepines (midazolam, triazolam)
- methylprednisolone (a corticosteroid)
- clopidogrel (used to reduce the risk of stroke or heart attack)
- ivabradine (used to lower the heart rate (see section 2, "Do not take")
- medicines used to suppress abnormal heart rhythm.

If you are due to have surgery, or visit your dentist, tell the doctor or dentist that you are taking DILZEM SR as it may interact with anaesthetics.

Pregnancy, breast-feeding and fertility
Do not take DILZEM SR if you are pregnant, think you may be pregnant, are planning to have a baby, or if you are breast-feeding.

Driving and using machines
DILZEM SR should not affect your ability to drive or use machines. However, if you feel faint or dizzy, do NOT drive or operate any machines.

DILZEM SR contains sucrose
If you have been told that you have an intolerance to some sugars, contact your doctor before taking DILZEM SR.

3. How to take DILZEM SR

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Adults suffering from high blood pressure or angina pectoris:
The recommended initial dose is one 90 mg capsule twice a day. Based on your response to the medicine, the doctor may increase the dose to a maximum of 180 mg twice daily, if required.

Always swallow the capsules **whole** with water.

Do not suck or chew the capsule or remove the contents, as this will affect the special release properties of the product.

Elderly patients
The recommended initial dose is 60 mg twice a day.

Patients with kidney or liver problems
The recommended initial dose is 60 mg twice a day. Diltiazem (active ingredient of this medicine) should be used with caution in patients with renal and hepatic impairment.

Use in children
DILZEM SR is NOT recommended for use in children.

If you take more DILZEM SR than you should
If you accidentally take too many DILZEM SR capsules, tell your doctor **immediately** or go to the nearest hospital accident and emergency department. Take along any capsules that are left, the container and the label so that the hospital staff can easily tell what medicine you have taken.

If you forget to take DILZEM SR
If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose (up to eight hours before), do NOT take the missed dose but take your next dose at your normal time. Do NOT take a double dose to make up for the forgotten one.

4. Possible side effects

Like all medicines, DILZEM SR can cause side effects, although not everybody gets them.

If you notice any of the following, **stop taking DILZEM SR and contact your doctor immediately**:
- signs of an **allergic reaction**:
  - swelling of the face, throat, lips, tongue or glands
  - skin rash, blistering affecting the skin, mouth, eyes, genitals or anus
  - sore throat and fever.
- signs of **liver problems**:
  - darkening of your urine
  - pale stools
  - yellowing of your skin or eyes.

Talk to your doctor straight away, if you notice any of the following:
- seeing, feeling or hearing things that are not there (hallucinations)
- mood changes (including depression), change in personality
- difficulty controlling movements and restlessness
- irregular heart beat
- low blood pressure
- redness, itching or scaling of the skin
- shortness of breath or chest pains (angina).

The frequency of these side effects is not known.

Other side effects include:

Very common (may affect more than 1 in 10 people):
- swelling of the ankles, feet or fingers.

Common (may affect less than 1 in 10 people):
- headache, dizziness
- a heart problem called "atrioventricular block", palpitations (feeling your heart beat)
- flushing
- constipation, indigestion, stomach pain, feeling sick (nausea)
- oedema (swelling due to excess fluids), feeling of weakness, tiredness.

Uncommon (may affect less than 1 in 100 people):
- nervousness, difficulty in sleeping
- bradycardia (slow heart beat)
- a fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- vomiting (being sick), diarrhoea
- blood tests which show changes in the way the liver is working.

Rare (may affect less than 1 in 1000 people):
- dry mouth, hives (lumpy, red, itchy skin).

Frequency not known:
- reduction in blood platelets, which increases risk of bleeding or bruising, high levels of white blood cells called eosinophils
- feeling unsteady on your feet, fainting, memory loss, tingling or numbness, sleepiness, shaking
- heart failure
- a disease of the blood vessels called vasculitis
- swollen, enlarged or bleeding gums
- increased sensitivity to sunlight, sweating
- swelling of breast tissue in men, loss of ability to have, or loss of interest in sex
- lazy eye, eye irritation
- increase of an enzyme called Creatine-Kinase (CK) in your blood, which may be a sign of muscle damage, weight gain
- nose bleed, blocked nose
- loss of appetite, increased blood sugar levels
- increased need to pass urine or an increased volume of urine, especially at night
- worsening of myasthenia gravis, muscle weakness or pain in muscles, bones or joints
- ringing or buzzing in the ears.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store DILZEM SR

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Keep out of the reach and sight of children.

Do not use DILZEM SR after the last day of the month shown in the expiry date printed on the carton and on the blister strips.

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. Contents of the pack and other information

What DILZEM SR contains
The active substance is diltiazem hydrochloride. Each DILZEM SR capsule contains 60 mg, 90 mg or 120 mg of diltiazem hydrochloride.
The other ingredients are: fumaric acid, talc, povidone, sugar spheres (containing sucrose and maize starch), ammonio methacrylate copolymer Type A, ammonio methacrylate copolymer Type B. The capsule shell contains yellow iron oxide (E172), erythrosine (E127), titanium dioxide (E171) and gelatin. The print ink contains shellac, black iron oxide (E172) and propylene glycol (E1520).

What DILZEM SR looks like and contents of the pack
DILZEM SR capsules are buff coloured hard gelatin capsules, printed with 60 mg, 90 mg or 120 mg and containing roughly spherical white to off-white beads. They are supplied in blister packs of 56 prolonged release capsules.

Marketing Authorisation Holder
Cephalon UK Limited
Ridings Point
Whistler Drive
Castleford
West Yorkshire
WF10 5HX
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Manufacturer

Teva UK Limited
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