Dilzem® 90 mg retard

Diltiazem hydrochloride

Prolonged release tablets

Reference Market:Germany

AfME Markets using same PLD

UAE, Bahrain, Kuwait, Oman, Qatar, Lebanon, Jordan

PACKAGE LEAFLET

Package leaflet: Information for the patient

Dilzem® 90 mg retard
Prolonged-release tablet
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 90 MG RETARD IS AND WHAT IT IS USED FOR

Dilzem 90 mg retard is a medicine to treat heart problems involving an insufficient supply of oxygen to the heart muscle as well as to treat high blood pressure.

Dilzem 90 mg retard is used in case of
-discomfort (such as pain or tightness in the chest area) during conditions involving an insufficient supply of oxygen to the heart muscle (angina pectoris)
  - during stress: chronic stable angina pectoris (stress angina)
  - at rest: unstable angina pectoris (crescendo angina, rest angina)
  - due to vascular spasm: vasospastic angina pectoris (Prinzmetal angina, variant angina)
- high blood pressure

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DILZEM 90 MG RETARD

Do not take Dilzem 90 mg retard

- if you are allergic to diltiazem hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if you experience relatively severe cardiac conduction disorders between your sinus node and the atria (2nd or 3rd degree SA block), unless you have a functioning pacemaker

- if you experience relatively severe cardiac conduction disorders between your atria and ventricles (2nd or 3rd degree AV block), unless you have a functioning pacemaker,
- if you suffer from a sinus node syndrome (cardiac arrhythmias as a result of a sinus node disorder), such as a heartbeat that has slowed to less than 60 beats per minute or alternating slowed or accelerated heartbeat or cardiac conduction disorders between your sinus node and atria, or failure of the sinus node to generate impulses (sinus bradycardia, bradycardia-tachycardia syndrome, SA blockages or sinus arrest), unless you have a functional pacemaker,
- if you have suffered from a shock,
- if you have suffered an acute heart attack with complications, such as slowed heartbeat (bradycardia), pronounced decrease in blood pressure (hypotension) or a heart muscle weakness of the left side of the heart (left ventricular failure),
- if you suffer from heart muscle weakness (manifest heart failure),
- if you suffer from atrial fibrillation/atrial flutter (cardiac arrhythmia as a result of an abnormally increased atrial excitation) and the simultaneous presence of a WPW syndrome (intermittent accelerated heartbeat due to accelerated conduction between your atrium and ventricle via an extra conduction system): this means there is an increased risk of an accelerated heartbeat being triggered in the ventricles (ventricular tachycardia),
- if you have a resting heart rate of under 50 beats per minute (bradycardia),
- if you are already taking a medicine that contains ivabradine (a medicine to treat certain heart disorders),
- if you are pregnant or breast-feeding (see "Pregnancy, breast-feeding and fertility"),
- if you are concomitantly receiving a medicine intravenously with the active substance dantrolene.

Note
Simultaneous intravenous administration of beta blockers during treatment with Dilzem 90 mg retard should be discontinued (see “Other medicines and Dilzem 90 mg retard”).

Warnings and precautions
Talk to your doctor or pharmacist before taking Dilzem 90 mg retard.

The following describes when you may take Dilzem 90 mg retard, which may only be taken under certain conditions and with particular caution. Talk to your doctor about this. This applies even if these statements previously applied to you:

- if you suffer from relatively mild cardiac conduction disorders between the sinus node and the atrium (1st degree SA block, risk of aggravation, or – in rare cases - a complete block), between the atria and the ventricles (1st degree AV block , risk of aggravation, and rarely, of a complete block) or within the ventricles (intraventricular conduction disorders, such as left or right bundle branch block),
- if you have a slowed heartbeat (risk of aggravation),
- if you have low blood pressure (systolic below 90 mmHg),
- if you are older than 60 years (the excretion of Dilzem 90 mg retard from the body will then be delayed), have prior kidney damage or abnormal liver function (see "How to take Dilzem 90 mg retard").
- if you are simultaneously being treated with beta blockers in tablet form (see "How to take Dilzem 90 mg retard").

Note
If you are being treated with Dilzem 90 mg retard and carbamazepine, midazolam, triazolam, afentanil, theophylline, cyclosporin A, digoxin, or digitoxin simultaneously, you should be monitored for symptoms of overdose on these medicines as a precautionary measure (see "Other medicines and Dilzem 90 mg retard").

Before general anaesthesia, tell the doctor responsible for the anaesthesia that you are currently being treated with diltiazem, as various body functions involving the heart and blood pressure, among other factors, may be affected with greater intensity.

Regular medical monitoring is necessary when you are being treated for high blood pressure with this medicine.

Elderly patients
The dose levels of Dilzem 90 mg retard must be carefully determined in elderly patients (older than 60 years) (see "How to take Dilzem 90 mg retard").

Other medicines and Dilzem 90 mg retard
Tell your doctor or pharmacist if you are taking/using or have recently taken/used any other medicines, including medicines obtained without a prescription.

Simultaneous treatment with Dilzem 90 mg retard may influence the effects of the following medicines or groups of medicines.

Certain medicines used to treat mental disorders (such as sleeping pills, tranquilisers, and medicines containing the active substance lithium).

Using the following medicines may intensify the effect and increase the risk of side effects:
- other simultaneously administered medicines that lower the blood pressure.
- medicines that negatively affect the strength of the heart, slow the heartbeat and/or inhibit cardiac conduction (AV conduction), such as beta blockers, medicines for treating cardiac arrhythmias (antiarrhythmics) or medicines for increasing the strength of the heart (cardiac glycosides such as digoxin, digitoxin): exacerbation of effects, such as relatively severe cardiac conduction disorders (AV block), slowing of the heartbeat, further reduction of the blood pressure, as well as the occurrence of heart muscle weakness (heart failure), may occur.
  Therefore, careful monitoring of the patient is advised when using diltiazem hydrochloride and these medicines simultaneously.
  Beta blockers should not be administered intravenously during treatment with diltiazem hydrochloride (see "Do not take Dilzem 90 mg retard").
- medicines that lower the cholesterol levels (HMG-CoA reductase inhibitors, the so-called statins, such as simvastatin, lovastatin or atorvastatin). Diltiazem hydrochloride may increase the concentrations of these medicines in your blood, which may intensify the effects or side effects of these medicines (statins)
- sirolimus, temsirolimus, everolimus (medicines that reduce the activity of the immune system): increased caution is required.
- carbamazepine (medicine for treating brain seizures), alfentanil (anaesthetic), theophylline (medicine for treating airway constriction), cyclosporin A (medicine for reducing transplant

rejection, which is also used to treat rheumatism), digoxin and digitoxin (medicines to strengthen the heart): The concentration of these medicines in the blood may increase. Therefore, as a precautionary measure it is important to watch for the symptoms of overdoses of these medicines. If necessary, the concentration of these medicines in the blood must be determined and the dose of the respective active substance reduced.
- rifampicin: There is a risk of reduced blood concentrations of diltiazem after treatment with rifampicin is started. You should be carefully monitored after starting or stopping treatment with rifampicin.
- nitrate derivatives: Increased blood pressure-lowering effect and a feeling of weakness. While you are taking diltiazem, nitrate derivatives should only be started by gradually increasing the dose.
- simultaneous treatment with alpha blockers may cause low blood pressure or intensify existing low blood pressure. The combination of diltiazem and an alpha blocker should not be considered, unless the blood pressure is closely monitored at frequent intervals.
- inhaled anaesthetics: In rare cases, this can lead to a drop in blood pressure (hypotension) or a slowing of the heartbeat (bradycardia).
- nifedipine: Diltiazem hydrochloride reduces the excretion rate (clearance) of nifedipine from the body.
  If the patient is being treated with both medicines simultaneously, then they must be carefully monitored and it may be advisable to reduce the dose of nifedipine.
- the effect of Dilzem 90 mg retard may be intensified if Dilzem 90 mg retard and cimetidine or ranitidine (medicines for stomach or duodenal ulcers) are taken simultaneously.

Weakening of the effect
The concentration of Dilzem 90 mg in the blood may be reduced if diazepam (sedative) is taken simultaneously.

Therefore, Dilzem 90 mg retard should not be taken together with any of the above-mentioned medicines unless your doctor has expressly ordered you to do so.

Note
After transplants, please take particular note of the following:
The plasma level of cyclosporin A may increase when treated with Dilzem 90 mg simultaneously. During long-term treatment with cyclosporin A and diltiazem hydrochloride (oral), the dose of cyclosporin A must be reduced in order to maintain a constant level of cyclosporin A. The dose reduction must be carried out specifically for the individual patient while monitoring the cyclosporin A level using a specific method (such as monoclonal antibodies).

Dilzem 90 mg retard with food, drink and alcohol

Do not consume any alcohol, if possible, while taking Dilzem 90 mg retard.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
There is only limited experience with the use of diltiazem hydrochloride in pregnant women. In 2 cases congenital heart defects were reported in newborns after diltiazem hydrochloride was taken in

the first trimester of pregnancy. Studies in animals with diltiazem hydrochloride have shown a harmful effect on the foetus. Therefore, do not take diltiazem hydrochloride during pregnancy (see "Do not take Dilzem 90 mg retard"). If you are of child-bearing age, a possible pregnancy must be ruled out by your doctor before you start treatment with diltiazem hydrochloride. You should use a suitable method of contraception while taking diltiazem hydrochloride.

Breast-feeding
Since diltiazem hydrochloride is excreted into human milk, do not take diltiazem hydrochloride while breast-feeding. If your doctor determines that it is absolutely necessary for you to use diltiazem hydrochloride while you are breast-feeding, you must stop breast-feeding (see "Do not take Dilzem 90 mg retard").

Fertility
Based on laboratory experiments transient dysfunctions of male fertility cannot be ruled out when diltiazem hydrochloride is administered over an extended period of time.

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

Driving and using machines
Even when used as intended, this medicine may impair your reactions enough to limit your ability to drive, operate machines or work without secure support. This is especially true at the start of treatment, when the dose is increased, the medicine is changed and when the medicine interacts with alcohol. No studies have been performed.

Dilzem 90 mg retard contains lactose monohydrate
This medicine contains lactose. Please check with your doctor before taking Dilzem 90 mg retard if you know that you suffer from intolerance to some sugars.

3. HOW TO TAKE DILZEM 90 MG RETARD

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

Unless your doctor tells you otherwise, the usual dose is:

Coronary heart disease
Take 1 Dilzem 90 mg retard prolonged-release tablet twice daily (equivalent to 180 mg diltiazem hydrochloride).

If the medicine's effect is insufficient, your doctor can increase the dose gradually up to a maximum of 4 Dilzem 90 mg retard prolonged-release tablets per day (equivalent to 360 mg diltiazem hydrochloride).

If you are in long-term treatment and have not experienced symptoms for a protracted period of time, it is recommended that your doctor review whether your daily dose can be reduced at 2 to 3-month intervals.

High blood pressure
Take 1 Dilzem 90 mg retard prolonged-release tablet twice daily (equivalent to 180 mg diltiazem hydrochloride).

If the decrease in blood pressure is not sufficient, your doctor can increase the dose gradually up to a maximum of 4 Dilzem 90 mg retard prolonged-release tablets per day (equivalent to 360 mg diltiazem hydrochloride).
After your blood pressure has been sufficiently lowered for a long period of time, it is recommended that your doctor review the possibility of reducing your dose.

Note
The dose of Dilzem 90 mg retard must be carefully determined in patients with liver and/or kidney disorders, as well as in elderly patients.

Method of administration
Swallow the prolonged-release tablets whole after meals with plenty of liquid (such as 1 glass of water).

Do not increase your dose unless your doctor tells you to.

Do not stop taking this medicine or change your dose unless your doctor tells you to.

Duration of administration
Treatment with Dilzem 90 mg retard is usually a long-term therapy.

Patients who suffer from angina pectoris in particular, should not stop taking Dilzem 90 mg retard abruptly; instead, the dose should be reduced gradually.

Talk to your doctor or pharmacist if you think that the effect of Dilzem 90 mg retard is too strong or too weak.

You may notice remains of the medication in your stool; however, this has no clinical relevance.

If you take more Dilzem 90 mg retard than you should

An overdose of diltiazem hydrochloride may lead to a severe drop in blood pressure (hypotension), slowed heartbeat (bradycardia), weakening of the heart muscle (heart failure), cardiac conduction disorders (AV block), possibly even cardiovascular arrest and renal impairment.

If you suspect that you have taken an overdose of Dilzem 90 mg retard, contact a doctor/emergency medical service immediately.
They can determine what measures are necessary, depending on severity of the overdose/toxicity.

If you forget to take Dilzem 90 mg retard
Do not take a double dose of Dilzem 90 mg retard to make up for a forgotten dose. Instead, continue to take the medicine as described in the dosage instructions or as prescribed by your doctor.

If you stop taking Dilzem 90 mg retard
Do not interrupt or stop treatment with Dilzem 90 mg retard without discussing this with your doctor beforehand.

Patients who suffer from angina pectoris in particular should not stop taking Dilzem 90 mg retard abruptly; instead, the dose should be reduced gradually.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The information on the frequency of side effects is based on the following categories:

Very common:	may affect more than 1 out of 10 treated persons
Common:	may affect up to 1 out of 10 treated persons
Uncommon:	may affect up to 1 out of 100 treated persons
Rare:	may affect up to 1 out of 1,000 treated persons
Very rare:	may affect up to 1 out of 10,000 treated persons
Not known:	frequency cannot be estimated from the available data

Psychiatric disorders

Uncommon:	Nervousness, insomnia, hallucinations, depressed mood, confusion, sleep disturbance
Not known:	Mood swings (including depression)

Nervous system disorders

Common:	Headaches, fatigue, dizziness and weakness
Not known:	Disturbance in the movement (Extrapyramidal syndrome), uncontrolled muscle twitching

Skin and subcutaneous tissue disorders

Common:	Reddening of areas of the skin (erythema), allergic skin reactions such as skin redness, itching and skin rashes (exanthema)
Rare:	Hives (urticaria)
Very rare:	Severe allergic skin reactions (such as exsudative erythema multiforme, Stevens-Johnson syndrome, epidermal necrolysis [Lyell's syndrome], skin lesions similar to lupus erythematosus)
Not known:	Photosensitivity (including lichenoid keratosis in areas of the skin exposed to the sun), angioneurotic oedema, rash, sweating, serious skin changes such as exfoliative dermatitis, acute exanthematous pustulosis, occasional desquamative erythema with or without fever

Reproductive system and breast disorders

Not known:	Enlarged breasts in males (gynecomastia)

Gastrointestinal disorders

Common:	Constipation, indigestion, stomach pain, nausea
Uncommon:	Gastrointestinal discomfort (vomiting, heartburn, diarrhoea)
Rare:	Dry mouth
Very rare:	Enlarged gums (gingival hyperplasia)

Hepatobiliary disorders

Uncommon:	Increase in liver enzymes (AST, ALT, LDH, ALP, gamma-GT and alkaline phosphate) as signs of acute liver damage Monitoring of liver parameters at regular intervals is advised.
Not known:	Hepatitis

Cardiac disorders

Common:	Cardiac conduction disorders (AV block), palpitations, fluid accumulations in the ankles or legs (ankle or leg oedema), particularly at higher doses and/or in patients with prior heart damage
Uncommon:	Slowed heartbeat (bradycardia)
Very rare:	cardiac conduction disorders (SA block), relatively severe drop in blood pressure (hypotension), fainting (syncope), decrease in the amount of blood pumped by the heart per minute (cardiac output decrease) or weakening of the heart muscle (heart failure), particularly at higher doses and/or in patients with prior heart damage

Vascular disorders

Common:	Redness of the skin (flush)
Uncommon:	Blood pressure regulation disorder when changing body positions (orthostatic hypotension)
Not known:	Inflammation of blood vessels (vasculitis including leukocytoclastic vasculitis)

Blood and lymphatic system disorders

Very rare:	Severe allergic reactions such as an increase in the number of certain white blood cells in the blood (eosinophilia) and lymph node swelling (lymphadenopathy)
Not known:	Reduced number of platelets (thrombocytopenia)

General disorders and administration site conditions

Very common: Peripheral oedema

Common:	General feeling of discomfort

Renal and urinary disorders

Very rare:	Erectile dysfunction

Metabolism and nutrition disorders

Very rare:	Elevated blood sugar (hyperglycaemia) Particular attention should be paid to this symptom in patients with diabetes mellitus.

If you notice any of the side effects listed above, do not take Dilzem 90 mg retard again. Tell your doctor so that they can evaluate the severity and decide which measures need to be taken.

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

5. HOW TO STORE DILZEM 90 MG RETARD

Keep this medicine out of the sight and reach of children.

Do not use Dilzem 90 mg retard after the expiry date which is stated on the carton and on the blister pack after "Use by". The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25 °C.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dilzem 90 mg retard contains
The active substance is diltiazem hydrochloride. One prolonged-release tablet contains 90 mg diltiazem hydrochloride.

The other ingredients are carmellose sodium, simethicone, hypromellose, lactose monohydrate, macrogol 6000, magnesium stearate (Ph. Eur.), hydrogenated castor oil, stearic acid (Ph. Eur.), talc, titanium dioxide (E 171).

What Dilzem 90 mg retard looks like and contents of the pack
The Dilzem 90 mg retard prolonged-release tablet is white, round and convex on both sides.

Dilzem 90 mg retard is available in packages of 30 and 100 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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This leaflet was last revised in April 2018.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the Pharmacist who sold the medicament.
- The doctor and the Pharmacist are experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach and sight of children

Council of Arab Health Ministers

Union of Arabic Pharmacists