

Package leaflet: Information for the user**Diltam 90mg Prolonged-release tablets**

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 Diltam is and what it is used for
2. What you need to know before you take Diltam
3. How to take Diltam
4. Possible side effects
5. How to store Diltam
6. Contents of the pack and other information

ROWEX®**1 What Diltam is and what it is used for**

Diltam contains the active substance diltiazem hydrochloride. It belongs to a group of medicines known as calcium channel blockers. It works by relaxing blood vessels so that blood passes through them more easily. This helps to lower your blood pressure. It also works by improving blood supply to the heart muscle which then receives more oxygen and as a result chest pain is prevented. Diltiazem does not provide immediate relief of chest pain from angina.

Diltam is used to treat:

- Mild to moderate high blood pressure
- A certain type of chest pain called angina

2 What you need to know before you take Diltam**Do not take Diltam if:**

- you are allergic to diltiazem or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: rash, swallowing or breathing problems, swelling.
- you have a very slow heartbeat - less than 40 beats per minute
- you have heart failure and problems with blood flow to your lungs. With these illnesses you may feel out of breath and have swollen ankles.
- you have any other serious problems with your heart. This includes having an uneven heartbeat (unless you have a pacemaker).
- you are having a medicine called dantrolene used for severe muscle spasms or severe fever.
- you are pregnant, think you may be pregnant, are planning to have a baby or are a woman of child-bearing age not using suitable contraception.
- you are already taking a medicine containing ivabradine for the treatment of certain heart diseases.

Warnings and precautions

Talk to your doctor or pharmacist before taking Diltam if:

- you have any other problem with your heart, apart from angina or those described in the previous section
- you are going to have an operation that requires a general anaesthetic
- you are at risk of having a blockage in the gut
- you are breast-feeding or planning to breast-feed

Your doctor will check you more closely particularly when you first start taking your tablets if:

- you are over 65 years old
- you have liver or kidney problems
- you have diabetes

If you are unsure if any of the above apply to you, talk to your doctor or pharmacist before taking Diltam.

Other medicines and Diltam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy

without a prescription, including herbal medicines. This is because Diltam can affect the way some other medicines work. Also some medicines can affect the way Diltam works.

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

- dantrolene (an infusion) used for severe muscle spasms or severe fever

Diltam may increase the effect of the following medicines:

- medicines for high blood pressure, such as beta-blockers and alpha- antagonists
- medicines used for an uneven heartbeat, such as amiodarone and digoxin
- nitrate derivatives (used for chest pains)
- medicines used to lower cholesterol such as simvastatin, fluvastatin and pravastatin
- ciclosporin used to stop the rejection of organs after a transplant
- carbamazepine used for epilepsy
- theophylline used for breathing problems
- lithium used for types of mental illness
- medicines used as sedatives or as sleeping aids, such as midazolam and triazolam
- methylprednisolone (corticosteroid)

The following medicines may make Diltam work less well:

- rifampicin (used for tuberculosis)

The following medicines can increase the effect of Diltam:

- medicines for stomach ulcers such as cimetidine and ranitidine
- ivabradine (for the treatment of certain heart diseases) - see section 2.

Diltam with food and drink

Do not take Diltam with grapefruit juice, as it may increase the chance of side effects.

Pregnancy and breast-feeding

Do not take Diltam if you are pregnant, think you may be pregnant, are planning to have a baby or are a woman of child-bearing age not using suitable contraception.

Breast-feeding should be avoided if you are taking Diltam. This is because small amounts may pass into mother's milk.

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 any medicine.

Driving and using machines

Be careful if you drive or operate machinery if you take this medicine. Side effects such as dizziness may interfere with this ability.

Diltam contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Diltam

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

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For oral use. Do not chew. Swallow the tablets whole with a little water.

Adults:

The recommended dose is one tablet twice daily. If necessary your doctor may increase this to two Diltam 90mg tablets twice daily.

Over 65 years or patients with liver or kidney problems:

Angina:

You may be started on a lower dose of 60mg twice daily. If necessary your doctor may increase this to one Diltam 90mg tablet twice daily.

High blood pressure:

You may be started on a dose of 120mg daily. If necessary your doctor may increase this to one Diltam 90mg tablet twice daily.

Children:

Diltam should not be given to children

If you take more Diltam than you should

If you take more tablets than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken. The following effects may happen: feeling dizzy or weak, blurred vision, chest pain, shortness of breath, fainting, an unusually fast or slow heartbeat, coma and confusion.

If you forget to take Diltam

If you forget a dose, take it as soon as you remember. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Diltam

Keep taking Diltam until your doctor tells you to stop. Do not stop taking it just because you feel better. If you stop, your illness may get worse.

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.

Stop taking this medicine and seek medical advice immediately if you experience:

- swelling of the face, lips, tongue and/or throat which may result in obstruction of the airways
- blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be an illness called 'Stevens-Johnson syndrome'.
- a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may feel generally unwell and have a fever, chills and aching muscles. This could be an illness called 'Toxic Epidermal necrolysis'.
- a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'.

Other side effects can be:

Very common: may affect more than 1 in 10 people

- swelling of the lower parts of your legs and arms

Common: may affect up to 1 in 10 people

- headache
- dizziness
- blockage in the heart known as atrioventricular block
- quick and strong heartbeat (palpitations)
- flushing
- constipation
- indigestion
- stomach pain
- nausea
- redness or inflammation of the skin
- feeling weak

Uncommon: may affect up to 1 in 100 people

- feeling more nervous than usual
- difficulty sleeping
- slow heartbeat

- feeling light-headed or faint when you stand up
- vomiting
- diarrhoea
- increase of certain liver enzymes

Rare: may affect up to 1 in 1,000 people

- dry mouth
- hives

Not known: frequency cannot be estimated from the available data

- reduced number of blood platelets
- mood changes (including depression)
- unusual movements of the tongue, muscle spasms in your face, rolling eyes and trembling
- blockage in the heart known as sinoatrial block
- congestive heart failure
- inflammation of blood vessels
- swollen gums
- passing large amounts of urine, excessive thirst and having a dry mouth or skin. These may be signs of high blood sugar
- inflammation of the liver
- being more sensitive to the sun than usual
- rash
- sweating
- an inflammatory skin disorder characterised by excessive peeling of the skin
- a rare skin rash causing blisters
- enlarged breasts in men

Reporting of side effects

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

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

Do not use this medicine after the expiry date which is stated on the carton and blister after Exp. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

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 Diltam contains

- The active substance is diltiazem hydrochloride. Each coated tablet contains 90 milligram diltiazem hydrochloride.
- The other ingredients are hydrogenated castor oil, lactose monohydrate (see section 2: 'Diltam contains lactose monohydrate'), povidone 25, macrogol 6000, microcrystalline cellulose, sodium starch glycolate, colloidal anhydrous silica, magnesium stearate. The film-coating is composed of hypromellose, microcrystalline cellulose (E460), stearic acid and titanium dioxide (E171).

What Diltam looks like and contents of the pack

Diltam 90mg Prolonged-release tablets are white, round, biconvex tablets with a score notch on one side. Diltam is available in blister packs containing 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder:
Rowex Ltd., Bantry, Co. Cork, Ireland

Manufacturers:

Salutas Pharma GmbH., Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

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