

Diltiazem Actavis

diltiazem hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Diltiazem Actavis. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Diltiazem Actavis against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Diltiazem Actavis is used for

The name of your medicine is Diltiazem Actavis. It contains the active ingredient called diltiazem hydrochloride.

Diltiazem Actavis belongs to a group of medicines called calcium channel blockers or calcium antagonists. They work by opening up blood vessels, which lowers blood pressure and lets more blood and oxygen reach the heart. They do not change the amount of calcium in your blood or bones.

Diltiazem Actavis is used to prevent angina.

Angina is a pain or uncomfortable sensation in the chest, often spreading to the arms or neck and sometimes to the shoulders and

back. The pain of angina is due to a shortage of oxygen to the heart.

Your doctor may have prescribed Diltiazem Actavis for another reason. Ask your doctor if you have any questions about why Diltiazem Actavis has been prescribed for you.

There is no evidence that Diltiazem Actavis is addictive.

This medicine is available only with a doctor's prescription.

Before you use Diltiazem Actavis

When you must not use it

Do not use Diltiazem Actavis if:

- 1. you have an allergy to diltiazem hydrochloride or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
 - swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
 - hives, itching or skin rash
 - fainting
- 2. you are pregnant, or intend to become pregnant.**

Diltiazem Actavis may affect your developing baby if you take it during pregnancy.

- 3. you are breast-feeding or intend to breast-feed.**

Diltiazem Actavis passes into

breast milk and may affect your baby.

Do not use Diltiazem Actavis if the packaging is torn or shows signs of tampering.

Do not use Diltiazem Actavis if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work (as well).

If you are not sure whether you should start using Diltiazem Actavis, contact your doctor.

Do not give these medicines to a child.

The safety and effectiveness of these medicines have not been established in children.

Before you start to use it

Tell your doctor if:

- 1. you have any allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

- 2. you are pregnant or intend to become pregnant.**

Diltiazem Actavis should not be used during pregnancy.

- 3. you are breast-feeding or plan to breast-feed.**

Your doctor will discuss the risks and benefits of using Diltiazem Actavis during breastfeeding. A decision will have to be made whether to discontinue breastfeeding or discontinue therapy taking into consideration the importance of the medicine.

- 4. you have or have had any medical conditions, especially the following:**

- Abnormal heart beat rhythm

- hypotension (low blood pressure)
- Heart attack or other heart-related complications
- Impaired renal (kidney) or hepatic (liver) function
- Diabetes

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Diltiazem Actavis. These include:

- Dantrolene (a muscle relaxant)
- Some other medicines for your heart or high blood pressure (eg. beta blockers, digoxin, amiodarone, nitrates)
- Cyclosporin, which you may have been given after an operation or because of rheumatoid arthritis
- Rifampicin (an antibiotic)
- Cimetidine or ranitidine (for ulcers or reflux)
- Diazepam (for depression, alcohol withdrawal or anxiety)
- Carbamazepine (for bipolar disorder or epilepsy)
- Lithium (for bipolar disorder)
- Theophylline (for asthma and other breathing problems)
- Certain drugs used to treat prostate problems
- Inhaled anaesthetic agents such as halothane, isoflurane, enflurane (for surgery)
- Drugs used to lower your blood cholesterol (including simvastatin, lovastatin)
- Benzodiazepines or medicines used as sedatives or to treat anxiety such as midazolam, triazolam
- Corticosteroids such as methylprednisolone, prednisone, cortisone
- Antiarrhythmics or medicines used to treat irregular heart beats

These medicines may be affected by Diltiazem Actavis, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Diltiazem Actavis.

How to take Diltiazem Actavis

How much to take

Diltiazem Actavis is usually taken 3 - 4 times a day. Take the prescribed dose as directed by your doctor.

A lower dosage may be required in elderly patients (over 65 years old).

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Swallow Diltiazem Actavis tablets whole with a glass of water.

When to take it

Take Diltiazem Actavis tablets at the same time each day as directed by your doctor.

How long to take it

Take Diltiazem Actavis for as long as your doctor tells you to.

Do not stop taking Diltiazem Actavis suddenly because this can bring on an attack of angina.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it

as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much Diltiazem Actavis. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much Diltiazem Actavis, you may feel dizzy and light-headed, feel pain in your left arm or chest or notice your heart beating very slowly. **If any of these occur you should get medical attention immediately.**

While you are using Diltiazem Actavis

Things you must do

Use Diltiazem Actavis exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, you may not get relief from your attacks of angina.

Tell your doctor if you continue to have angina attacks or if they become more frequent while you are using Diltiazem Actavis.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Diltiazem Actavis.

Tell your doctor or pharmacist that you are taking Diltiazem Actavis if you are about to be started on any new medicines.

Things you must not do

Do not use it to treat any other complaints unless your doctor says to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

As mentioned previously, do not suddenly stop taking your medicine since this can cause severe angina for a day or two.

Things to be careful of

Be careful driving or operating machinery until you know how Diltiazem Actavis affects you.

Diltiazem Actavis may cause dizziness and fainting in some patients, especially when you first start to use it. Make sure you know how you react to Diltiazem Actavis before you drive a car, operate machinery, or do anything else that could be dangerous if this happens to you.

Be careful not to overdo physical activities when you first start using Diltiazem Actavis.

You may feel better when you start taking it, but you will need time to improve your physical fitness.

Get up slowly when getting out of bed or standing up if you feel light-headed, dizzy or faint.

If this is a problem and it gets worse or continues, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Diltiazem Actavis.

Diltiazem Actavis helps most people with angina, but it may have unwanted effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- swelling or flushing (feeling hot suddenly)
- headache
- nausea, vomiting, constipation, diarrhoea, indigestion, gastric pain
- dizziness
- confusion, hallucinations, abnormal dreams, mental depression or mood changes
- trouble sleeping
- nervousness, tremor
- ringing or other persistent noise in the ears
- loss of memory
- dry mouth
- loss of appetite
- weight increase
- increased sensitivity to the sun
- unusual movements or uncontrollable movements
- rash or an itchy, burning or prickly sensation
- small round, raised itchy areas on the skin
- weakness or tiredness

These are the more common side effects of Diltiazem Actavis. These side effects are usually mild.

If any of the following happen, stop taking Diltiazem Actavis and tell your doctor immediately or go to casualty at your nearest hospital:

- you feel continuously light headed or dizzy
- you notice your heart beating irregularly, slowly or very quickly
- you feel pain, which may be severe, in your left arm and chest
- you have blisters and bleeding in the lips, eyes, mouth, nose or genitals
- you have skin reactions such as red, painful or itchy spots, blisters or peeling of the skin.

These are very serious side effects. You may need urgent medical

attention or hospitalisation. These side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking Diltiazem Actavis

Storage

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of their blister pack they may not keep well.

Keep Diltiazem Actavis in a cool, dry place where it stays below 25°C. Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Diltiazem Actavis, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

Diltiazem Actavis 60mg tablets are white, film coated, capsule shaped and scored with one face embossed DL/60.

Diltiazem Actavis 60mg tablets are available in blister packs of 90 tablets.

Ingredients

Diltiazem Actavis 60mg tablets contain 60mg of the active ingredient diltiazem hydrochloride.

Other ingredients in Diltiazem Actavis 60mg tablets are:

- aluminium hydroxide - dried
- castor oil - hydrogenated
- lactose
- magnesium stearate
- methacrylic acid copolymer
- Opadry white Y-1-7000B (hypromellose, titanium dioxide, macrogol 400, indigo carmine CI73015)
- talc – purified

Diltiazem Actavis does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Anneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141
Australia

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Diltiazem Actavis 60mg tablets
(blister pack) AUST R 184097