SCHEDULING STATUS

S3

ADCO ZILDEM 180 SR, Sustained Release Capsule
ADCO ZILDEM 240 SR, Sustained Release Capsule
Diltiazem hydrochloride

Contains sugar (sucrose):
ADCO ZILDEM 180 SR: 81,09 mg per sustained release capsule
ADCO ZILDEM 240 SR: 108,12 mg per sustained release capsule

Read all of this leaflet carefully before you start taking ADCO ZILDEM SR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ADCO ZILDEM SR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ADCO ZILDEM SR is and what it is used for

ADCO ZILDEM SR is used for the prevention of angina (chest pain caused by reduced blood flow to the heart), including Prinzmetal's angina (chest discomfort or pain during rest) and to treat mild to moderate high blood pressure.
ADCO ZILDEM SR contains the active ingredient diltiazem hydrochloride and belongs to a class of medicines known as calcium-channel blockers. ADCO ZILDEM SR works by blocking calcium from entering the cells of the heart and blood vessel walls. This causes the walls to dilate i.e., make them wider and in turn, increases supply of oxygen and blood to the heart, as well as, lower blood pressure.

2. What you need to know before you take ADCO ZILDEM SR

Do not take ADCO ZILDEM SR:

- if you are hypersensitive (allergic) to diltiazem hydrochloride or any of the other ingredients of ADCO ZILDEM SR (listed in section 6).
- if you are pregnant or planning to fall pregnant (see section: 'Pregnancy, breastfeeding and fertility').

- if you are breastfeeding or planning to breastfeed (see section: ‘Pregnancy, breastfeeding and fertility’).
- if you have decompensated heart failure, severe bradycardia (a slower than normal heartbeat; less than 40 beats/min), sick sinus syndrome (a condition which results in an irregular heartbeat), second- or third-degree AV block (a condition which affects the way in which the heart beats), except if you have a functioning ventricular pacemaker.
- if you have left-sided heart failure with pulmonary congestion (excess fluid in the lungs causing impaired breathing).
- if you are undergoing an infusion of dantrolene (a muscle relaxant).
- if you have an accessory bypass i.e. Wolf-Parkinson-White syndrome or short PR syndrome (abnormal heart rhythms or arrhythmias) and/or atrial fibrillation or flutter (uncoordinated or irregular contractions of the upper chambers of the heart), you should not be given intravenous (IV) diltiazem hydrochloride.
- if you are already taking a medicine containing ivabradine used for the treatment of certain heart diseases (see section: ‘Other medicines and ADCO ZILDEM SR).
- if you are already taking a medicine containing lomitapide used for the treatment of high cholesterol levels (see section: ‘Other medicines and ADCO ZILDEM SR).
- if you are already taking a medicine containing asunaprevir used for the treatment of hepatitis C virus infection (see section: ‘Other medicines and ADCO ZILDEM SR).
- if you have severe impaired liver and kidney function.
- if you have a condition called porphyria (a metabolic disorder).
- if you are a child, as safety in children has not been established.

Warnings and precautions

Take special care with ADCO ZILDEM SR:

- if you are going to have an operation and require general anaesthesia. Ensure that the surgeon knows you are taking ADCO ZILDEM SR.
- if you are at risk of mood changes, including depression.
- if you are risk of gut problems.

Your doctor will closely monitor how you respond to your treatment if:

- you 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.
- you have reduced left ventricular function (a condition that affects how well the heart pumps out blood to the body).
- you have bradycardia (slower than normal heart beat).
- you have first degree heart block (a condition in which the nerve signals to the heart are disturbed, causing irregular heartbeats) or any previous unusual electrocardiogram (ECG) tests, such as prolonged PR intervals.
- you are an elderly person.
- you have kidney or liver problems.
- you have diabetes.

- you ever had asthma.

ADCO ZILDEM SR can also inhibit bowel movements, so tell your doctor if you know that you are having the risk of developing a bowel obstruction (e.g., if you suffer from constipation).
You may notice remains of the capsules in your stools, but this is nothing to worry about.

Children and adolescents
ADCO ZILDEM SR is not recommended for use in children below 18 years due to a lack of data on safety and efficacy.

Other medicines and ADCO ZILDEM SR
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Tell your doctor or pharmacist if you are currently using:

- Angiotensin-converting enzyme (ACE) inhibitors such as lisinopril or captopril.
- Diuretics (“water tablets”) such as frusemide or spironolactone.
- Alpha blockers such as prazosin, because these are also used to treat high blood pressure and could cause hypotension (low blood pressure) if used together with ADCO ZILDEM SR.
- Digoxin, used for heart conditions and heart failure.
- Other medicines used to treat high blood pressure or to treat a heart condition such as beta blockers (e.g. propranolol) or antiarrhythmic medicines (e.g. amiodarone).
- Theophylline, used to treat breathing difficulties such as asthma.
- Carbamazepine, which is used to treat epilepsy and bipolar disorder (a psychiatric condition).
- Cyclosporin, tacrolimus and sirolimus which may be used following organ transplants to help prevent rejection.
- Medicines used to treat heartburn or stomach ulcers such as cimetidine, as these can increase blood levels of diltiazem.
- Dantrolene infusion – a muscle relaxant. ADCO ZILDEM SR and dantrolene should not be taken together.
- Medicines containing ivabradine used for the treatment of certain diseases.
- 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.
- Medicines containing asunaprevir used for the treatment of hepatitis C virus infection. Diltiazem may increase the concentration of the asunaprevir that may lead to an increase in the likelihood and severity of liver related side effects.
- Lithium – used to treat depression.
- Nitrate derivatives - used for the short-term symptomatic relief of angina pectoris.
- Other antiarrhythmic medicines such as verapamil.
- Rifampicin – an antibiotic and used to treat tuberculosis (TB).

- Tricyclic antidepressants such as imipramine and amitriptyline.
- Phenytoin used for epilepsy.
- Iodinated contrast media (used for tests involving x-rays).
- Antiplatelet medicines used to reduce the chance of blood clots forming, such as aspirin or clopidogrel.
- Benzodiazepines (tranquilisers) such as midazolam and triazolam.
- Corticosteroids such as methylprednisolone.
- Statins such as simvastatin, atorvastatin and fluvastatin which are used to lower cholesterol levels in the body.
- Erythromycin which is used to treat infections.
- Cilostazol used for intermittent cramp-like pain in your legs when you walk caused by insufficient blood supply in your legs.
- Any other CYP450 inhibitors as this may increase the concentration of diltiazem in your blood that may lead to side effects even at normal doses.

Inform your anaesthetist that you are using ADCO ZILDEM SR before you go for an operation.

ADCO ZILDEM SR with food and drink
It is advisable to limit the amount of grapefruit juice you drink while taking ADCO ZILDEM SR as it can increase the blood levels of the active ingredient diltiazem, and may increase your chance of getting side effects.
If you are concerned, you should stop drinking grapefruit juice and consult your doctor.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
You should not take ADCO ZILDEM SR if you are pregnant, think you may be pregnant, or if you are planning to become pregnant.
You should not take ADCO ZILDEM SR if you are breastfeeding. This is because small amounts may pass into mothers' milk. If ADCO ZILDEM SR has been prescribed to you and you are breastfeeding, then an alternative way to feed your infant (other than breastfeeding) must be considered.

There is no information available on the effects of fertility.

Driving and using machines
ADCO ZILDEM SR may cause dizziness or make you feel unwell, thereby impairing your ability to drive a vehicle or use machines. Do not drive or operate machinery until you know how ADCO ZILDEM SR will affect you.

ADCO ZILDEM SR contains sucrose
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 ADCO ZILDEM SR
Do not share medicines prescribed for you with any other person.
Always take ADCO ZILDEM SR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For the treatment of angina and hypertension:
The usual dose of ADCO ZILDEM SR will be one 240 mg capsule per day or one 180 mg capsule once or twice a day. The usual maximum dose is 360 mg per day.
Once the daily dose has been optimised, your doctor may substitute your ADCO ZILDEM SR where appropriate.
The capsules should be swallowed whole with a glass of water.
If your doctor prescribes a different daily dose make sure you know how many capsules you need to take.
If you are not sure, it is very important that you ask your doctor or pharmacist for advice.
Your doctor should monitor you, and may change your dose depending on how well ADCO ZILDEM SR works for you.
If needed, you may be given a different strength of ADCO ZILDEM SR capsules.
If you are elderly or have liver or kidney problems, you will usually be prescribed a lower starting dose.

Your doctor will tell you how long your treatment with ADCO ZILDEM SR will last. Do not stop treatment early without consulting your health care provider first.
If you have the impression that the effect of ADCO ZILDEM SR is too strong or too weak, tell your doctor or pharmacist.

If you take more ADCO ZILDEM SR than you should
In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
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 (due to low blood pressure), blurred vision, chest pain, shortness of breath, fainting, an usually fast or slow heartbeat, slurred speech, confusion, decreased kidney function, coma, and sudden death.
The levels of sugar in your blood may also rise and may require treatment.
You may only experience symptoms of overdose several hours after ingestion.

Treatment of overdose is symptomatic and supportive.
If you have ingested a substantial overdose of ADCO ZILDEM SR, you may be hospitalized for observation.
Symptoms such as low blood pressure, high blood sugar levels and slow heartbeat will be managed by receiving the appropriate treatment.

If you forget to take ADCO ZILDEM SR
Do not take a double dose to make up for the forgotten individual doses.

If you stop taking ADCO ZILDEM SR
Talk to your doctor before you stop taking ADCO ZILDEM SR.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects
ADCO ZILDEM SR can have side effects.
Not all side effects reported for ADCO ZILDEM SR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ADCO ZILDEM SR, please consult your health care provider for advice.

If any of the following happens, stop taking ADCO ZILDEM SR and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ADCO ZILDEM SR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:
Frequent side effects:
- Dizziness
- Headache
- First-degree, second-degree or third-degree atrio ventricular block (heart rhythm disorders)
- Bundle branch block (a condition where there is a delay or blockage along the pathway that electrical impulse travel to make the heart beat)
- Palpitations (a forceful heartbeat that may be rapid or irregular)
- Flushing (reddening of the skin)
- Constipation
- Indigestion
- Nausea
- Gastric discomfort (abdominal pain)
- Erythema (reddening of the skin)
- Peripheral oedema (swelling especially of the ankles and feet caused by a fluid build-up)
- Feeling generally unwell

Less frequent side effects:

- Nervousness
- Insomnia (difficulty sleeping)
- Bradycardia (slow heartbeat)
- Orthostatic hypotension (feeling dizzy or lightheaded on standing or sitting up because of a drop in blood pressure)
- Bronchospasm (excessive and prolonged contraction of the airway muscles causing difficulty breathing), including worsening of asthma
- Dry mouth
- Vomiting
- Diarrhoea
- Increase in certain liver enzyme levels such as AST, ALT, LDH and ALP

Side effects occurring with unknown frequency:

- Thrombocytopenia (low levels of blood platelets)
- Hyperglycaemia (high blood sugar levels)
- Mood changes including depression
- Reports of hyperactivity (being distracted, unable to concentrate, aggressive, etc.), sometimes associated with psychiatric symptoms
- Extrapyramidal syndrome (tremor, muscle spasms or movement disorders)
- Confusion
- Drug-induced Parkinsonism (tremors, muscle stiffness, slowness of movement, impaired balance and coordination, etc.)
- Congestive heart failure (when the heart does not pump blood properly) or heart attack
- Sinoatrial block and sinus arrest (heart rhythm problems in which the heartbeat is too slow, or either pauses or stops)
- Ankle oedema (swelling in the ankles due to a build-up of fluid); can be more frequent in the elderly
- Vasculitis (inflammation of the blood vessels), including leukocytoclastic vasculitis (inflammation of the small blood vessels)
- Heartburn
- Gingival hyperplasia (overgrowth of the gum tissue)
- Inflammation of the liver
- Rash
- Photosensitivity (sunburn-like reactions following exposure to light), including lichenoid keratosis (a benign skin lesion that occurs as a small gray-brown plaque or papule and most commonly found on the chest or upper extremities)
- Angioneurotic oedema (rapid swelling under the skin)
- Erythema multiforme (a skin reaction characterised by bull’s eye shaped lesions)
- Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash) and toxic epidermal necrolysis (life-threatening condition characterised by extensive exfoliation of the skin)

- Sweating
- Exfoliative dermatitis (redness and flaking of the skin)
- Exanthematous pustulosis (small pus-filled spots on the skin and rash)
- Hyperpigmentation (darkened patches or spots on the skin)
- Desquamative erythema with or without fever (peeling of skin)
- 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').
- Gynaecomastia (abnormal breast enlargement in men)
- Increase of certain enzymes in the body

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of ADCO ZILDEM SR.

5. How to store ADCO ZILDEM SR
- Store all medicines out of reach of children.
- Store in a cool dry place at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What ADCO ZILDEM SR contains
The active substance is diltiazem.
ADCO ZILDEM 180 SR: Each sustained release capsule contains 180 mg diltiazem hydrochloride.
ADCO ZILDEM 240 SR: Each sustained release capsule contains 240 mg diltiazem hydrochloride.

The other ingredients are erythrosine (E127), ethylcellulose, gelatine, indigo carmine (E132), povidone K 30, shellac, sugar spheres, talc, titanium dioxide.

What ADCO ZILDEM SR looks like and contents of the pack
Hard gelatin capsules.
ADCO ZILDEM 180 SR: Size 1 hard gelatin capsules, natural transparent cap and opaque pink body filled with white-grey to light yellow granules.
ADCO ZILDEM 240 SR: Size 0 hard gelatin capsules, natural transparent cap and scarlet

opaque body filled with white-grey to light yellow granules.

ADCO ZILDEM SR capsules are packaged in PVC/PVDC blister packs on aluminium foil packed into individual cartons in strips of 10 capsules.
Pack sizes of 30 and 100 capsules.

Holder of Certificate of Registration
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