SCHEDULING STATUS

S3

ADCO ZILDEM 180 SR, Sustained Release Capsules
ADCO ZILDEM 240 SR, Sustained Release Capsules
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

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 antidysrhythmic 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.

Adults
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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. 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 (E171).

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.
Not all pack sizes are marketed.

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road
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Midrand, 1685
Customer Care: 0860 ADCOCK / 232625

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Registration numbers
ADCO ZILDEM 180 SR: 30/7.1/0183
ADCO ZILDEM 240 SR: 30/7.1/0184

Namibia:

ADCO ZILDEM 180 SR: 05/7.1/0274 **NS2**
ADCO ZILDEM 240 SR: 05/7.1/0275 **NS2**

SKEDULERINGSTATUS

S3

ADCO ZILDEM 180 SR, Kapsules met volgehoue vrystelling
ADCO ZILDEM 240 SR, Kapsules met volgehoue vrystelling
Diltiazemhidrochloried

Bevat suiker (sukrose):
ADCO ZILDEM 180 SR: 81,09 mg per kapsule met volgehoue vrystelling
ADCO ZILDEM 240 SR: 108,12 mg per kapsule met volgehoue vrystelling

Lees die hele voubiljet noukeurig voordat u ADCO ZILDEM SR gebruik
- Hou hierdie voubiljet. U mag dit weer moet lees.
- Vra asseblief u dokter, apteker, verpleegster of ander gesondheidsorgverskaffer as u enige verdere vrae het.
- ADCO ZILDEM SR is aan u persoonlik voorgeskryf en u moet nie u medisyne met enige ander persoon deel nie. Dit kan hulle skaad al het hulle dieselfde simptome as u.

Wat in hierdie voubiljet is

1. Wat ADCO ZILDEM SR is en waarvoor dit gebruik word
ADCO ZILDEM SR word gebruik vir die voorkoming van angina (borspyn wat deur verminderde bloedvloei na die hart veroorsaak word), wat Prinzmetal se angina (ongemak in die bors en pyn gedurende rus) en om ligte tot matige hoë bloeddruk te behandel.
ADCO ZILDEM SR bevat die aktiewe bestanddele diltiazemhidrochloried en behoort tot ’n klas medisyne bekend as kalsium-kanaal-blokkers. ADCO ZILDEM SR werk deur te keer dat kalsium die selle van die hart en bloedvatwande binne gaan. Dit veroorsaak dat die wande verwyd, d.i., maak hulle wyer en verhoog op sy beurt die toevoer van suurstof en bloed na die hart, asook dat die bloeddruk verlaag.

2. Wat u moet weet voordat u ADCO ZILDEM SR gebruik
Moenie ADCO ZILDEM SR gebruik nie:
- as u hipersensitief (allergies) vir diltiazemhidrochloried of enige van die ander bestanddele van ADCO ZILDEM SR (in afdeling 6 gelys) is.
- as u swanger is of beplan om swanger te raak (sien afdeling: ‘Swangerskap, borsvoeding en vrugbaarheid’).

- as u borsvoed of beplan om te borsvoed (sien afdeling: ‘Swangerskap, borsvoed en vrugbaarheid’).
- as u gedekompenseerde hartversaking, erge bradikardie (’n stadiger as normale hartklop; minder as 40 kloppe/min), siek sinus-sindroom (’n toestand wat ongereelde hartklop veroorsaak), tweede- of derdegraadse AV-blokkasie (’n toestand wat die manier hoe die hart klop beïnvloed), behalwe as u ’n werkende ventrikulêre pasaangeër het.
- as u linkerkantse hartversaking met pulmonale kongestie (oorvloed vog in die longe wat asemhaling belemmer) het.
- as u infusie van dantroleen (’n spierverslapper) ondergaan.
- as u ’n bykomstige omleiding het, d.i. Wolf-Parkinson-White sindroom of kort PR sindroom (abnormale hartritmes of aritmieë) en/of atriale fibrillasie of fladder (ongekoördineerde of ongereelde sametrekkings van die boonste kamers van die hart) het, moet u nie binneaarse (IV) diltiazemhidrochloried ontvang nie.
- as u alreeds medisyne wat ivabradien, wat vir behandeling van sekere hartsiektes gebruik word, bevat, gebruik (sien afdeling: ‘Ander medisyne en ADCO ZILDEM SR).
- as u alreeds medisyne wat lomitapied bevat, wat vir die behandeling van hoë cholesterolvlakke gebruik word, gebruik (sien afdeling: ‘Ander medisyne en ADCO ZILDEM SR).
- as u alreeds medisyne wat asunaprevir bevat, wat vir behandeling van hepatitis C virus-infeksie gebruik word, gebruik (sien afdeling: ‘Ander medisyne en ADCO ZILDEM SR).
- as u ernstige verswakte lewer- of nierfunksie het.
- as u ’n toestand genaamd porfirie (’n metaboliese versteuring) het.
- as u ’n kind is, want veiligheid vir kinders is nie vasgestel nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met ADCO ZILDEM SR:
- as u ’n operasie moet ondergaan en algemene narkose nodig het. Verseker dat die sjirurg bewus is dat u ADCO ZILDEM SR gebruik.
- as u ’n risiko loop van gemoedsverandering, insluitend depressie.
- as u ’n risiko van derm-probleme loop.

U dokter sal u reaksie op die behandeling fyn dophou as:
- u ’n geskiedenis van hartversaking, nuwe kortasemtoestand, stadige hartklop of lae bloeddruk het. Aangesien gevalle van nier-beskadiging by pasiënte met sulke toestande aangemeld is, sal u dokter dit moontlik nodig vind om u nierfunksie te monitor.
- u verminderde linker ventrikulêre funksie (’n toestand wat beïnvloed hoe goed die hart bloed na die liggaam pomp).
- u bradikardie (stadiger as normale hartklop) het.
- u eerstegraadse hartblokkasie (’n toestand waar die senuwee-seine na die hart onderbreek word, wat ongereelde hartklop tot gevolg het) of enige vorige buitengewone elektrokardiogram (EKG)-toetse, soos verlengde PR-intervalle het.
- u bejaard is.
- u nier- of lewerprobleme het.

- u diabetes het.
- u ooit asma gehad het.

ADCO ZILDEM SR kan ook dermfunksie belemmer, so vertel u dokter as u weet dat u die risiko loop om derm-blokkasie te kry (bv. u kan aan hardlywigheid ly).
U kan oorblyfsels van die kapsule in u stoelgange opmerk, maar dit is niks om oor bekommerd te wees nie.

Kinders en adolessente
ADCO ZILDEM SR word nie vir gebruik deur kinders jonger as 18 jaar oud aanbeveel nie as gevolg van ’n tekort aan data oor die veiligheid en doeltreffendheid.

Ander medisyne en ADCO ZILDEM SR
Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in.)
Vertel u dokter of apteker as u tans die volgende gebruik:
- Angiotensien-omskakelende ensiem (ACE)-inhibeerders soos lisinopril of kaptopril.
- Diuretika (“waterpille”) soos frusemied of spironolaktoon.
- Alfa blokkers soos prazosien, want hulle word ook gebruik om hoë bloeddruk te behandel en kan hipotensie (lae bloeddruk) veroorsaak as dit saam met ADCO ZILDEM SR gebruik word.
- Digoxin, wat gebruik word om hart toestande en hartversaking te behandel.
- Ander medisyne wat gebruik word vir behandeling vir hoë bloeddruk of hartkondisies soos beta blokkers (bv. propranolol) of antidisritmiese medisynes (bv. amiodarone).
- Teofillien, wat gebruik word om asemhalingsprobleme soos asma te behandel.
- Karbamasepien, wat gebruik word vir behandeling van epilepsie en bipolêre versteuring (’n psigiatriese toestand).
- Siklosporien, takrolimus en sirolimus, wat gebruik word om verwerping na orgaanoorplanting te voorkom..
- Medisyne wat gebruik word om sooibrand of maagsere te behandel soos simetidien, want hulle kan die vlakke van diltiazem in die bloed verhoog.
- Dantroleen-infusie – ’n spierverslapper. ADCO ZILDEM SR en dantroleen moenie saam gebruik word nie.
- Medisynes wat ivabradien wat vir die behandeling van sekere siektes gebruik word bevat.
- Medisynes wat lomitapied bevat en wat vir die behandeling van hoë cholesterol vlakke gebruik word. Diltiazem kan die konsentrasie van lomitapied verhoog wat tot die verhoging van die waarskynlikheid en erns van lewer-verwante newe-effekte kan lei.
- Medisynes wat asunaprevir bevat en gebruik word vir die behandeling van hepatitis C-virus infeksie. Diltiazem kan die konsentrasie van asunaprevir verhoog en tot ’n verhoging van die waarskynlikheid en erns van lewer-verwante newe-effekte kan lei.
- Litium – wat gebruik word om depressie te behandel.
- Nitraat-afleidings wat gebruik word vir die korttermyn simptomatiese verligting van angina pectoris.

- Ander antiaritmiese medisynes soos verapamil.
- Rifampicin – ’n antibiotikum wat vir die behandeling van tuberkulose (TB) gebruik word.
- Drie-sikliese antidepressante soos imipramien en amitriptilien.
- Fenitoïen wat vir epilepsie gebruik word.
- Jodiumhoudende kontrasmedia (wat vir toetse wat x-strale behels gebruik word).
- Antiplaatjie medisynes wat gebruik word om die kans van bloedklontvorming te verminder, soos asperien of klopidogrel.
- Bensodiasepiene (kalmeermiddels) soos midazolam en triazolam.
- Kortikosteroïede soos metielprednisoloon.
- Statiene soos simvastatien, atorvastatien en fluvastatien wat gebruik word om die cholesterolvlakke in die liggaam te verlaag.
- Eritromisien wat gebruik word om infeksies te behandel.
- Cilostazol wat gebruik word om afwisselende krampagtige pyn in u bene wanneer u loop veroorsaak as gevolg van onvoldoende bloedtoevoer na u bene.
- Enige ander CYP450-inhibeerders kan die konsentrasie van diltiazem in u bloed verhoog wat tot newe-effekte, selfs teen normale dosisse, kan lei.

Stel u narkotiseur in kennis as u ADCO ZILDEM SR gebruik voordat u ’n operasie ondergaan.

ADCO ZILDEM SR met kos en drank
Dit word aanbeveel om die hoeveelheid van pomelosap wat u tydens gebruik van ADCO ZILDEM SR drink te beperk want dit kan die vlakke van die aktiewe bestanddeel diltiazem in u bloed kan verhoog, en dit kan u kans om newe-effekte verhoog.
U moet ophou om pomelosap te drink en u dokter raadpleeg as u bekommerd is.

Swangerskap, borsvoeding en vrugbaarheid
Raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer voor u hierdie medisyne gebruik as u swanger is of borsvoed, dink u kan dalk swanger wees of beplan om ’n baba te hê.
U moenie ADCO ZILDEM SR gebruik as u swanger is, dink u kan dalk swanger wees of beplan om swanger te raak nie.
U moenie ADCO ZILDEM SR gebruik as u borsvoed nie. Dit is omdat klein hoeveelhede na die moedersmelk oorgedra kan word. As ADCO ZILDEM SR aan u voorgeskryf is en u borsvoed, moet ’n ander metode van voeding (anders as borsvoeding) vir u baba oorweeg word.

Daar is geen inligting beskikbaar oor die uitwerking op vrugbaarheid nie.

Bestuur en gebruik van masjinerie
ADCO ZILDEM SR kan duiseligheid veroorsaak of u siek laat voel, en so u vermoë om ’n voertuig te bestuur of om masjinerie te gebruik beïnvloed. Moenie bestuur of masjinerie bedryf tot u weet tot watter mate ADCO ZILDEM SR u sal beïnvloed nie.

ADCO ZILDEM SR bevat sukrose
Kontak u dokter voordat u hierdie medisinale produk gebruik as u ingelig is dat u ’n intoleransie vir sommige suikers het.

3. Hoe om ADCO ZILDEM SR te gebruik
Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.
Gebruik ADCO ZILDEM SR altyd presies soos deur u dokter of apteker voorgeskryf is.
Bevestig met u dokter of apteker as u onseker is.

Volwassenes
Vir die behandeling van angina en hipertensie:
Die gewone dosis van ADCO ZILDEM SR sal een 240 mg kapsule per dag of een 180 mg kapsule een of twee keer per dag wees. Die normale maksimum dosis is 360 mg per dag.
As u daaglikse dosis geoptimaliseer is kan u dokter u ADCO ZILDEM SR vervang waar van toepassing.
Die kapsules moet heel gesluk word met ’n glas water.
As u dokter ’n verskillende daaglikse dosis voorskryf, moet u seker maak dat u weet hoeveel kapsules u moet neem.
Dit is baie belangrik dat u u dokter of apteker vir advies raadpleeg as u nie seker is nie.
U dokter moet u monitor, en kan u dosis aanpas, afhangende van hoe goed ADCO ZILDEM SR vir u werk
Indien nodig kan u ’n verskillende sterkte van ADCO ZILDEM SR kapsules gegee word.
As u bejaard is of lewer- of nierprobleme het sal ’n laer aanvangsdosis gewoonlik voorgeskryf word.

U dokter sal vir u sê hoe lank u behandeling met ADCO ZILDEM SR sal duur. Moenie vroeg ophou met die behandeling sonder om eers u gesondheidsorgverskaffer te raadpleeg nie.
Vertel u dokter of apteker as u die indruk kry dat die uitwerking van ADCO ZILDEM SR te sterk of te swak is.

As u meer ADCO ZILDEM SR gebruik as wat u moet
Raadpleeg u dokter of apteker in die geval van oordosering. Kontak die naaste hospitaal of gifsentrum indien nie een van hulle beskikbaar is nie.
Neem die medisyne pak saam. Dit is sodat die dokter kan weet wat u geneem het. Die volgende kan gebeur: duiselig of swak gevoel (as gevolg van lae bloeddruk), versteurde sig, borspyn, kortasem, floute, ’n ongewone vinnige of stadige hartklop, onduidelike spraak, verwarring, verminderde nierfunksie, koma, en skielike dood..
Die vlakke van suiker in u bloed kan ook toeneem en mag behandeling benodig.
U kan simptome van oordosering eers ure na inname ervaar.

Behandeling vir oordosering is simptomaties en ondersteunend.
As u ’n beduidende oordosis-hoeveelheid van ADCO ZILDEM SR ingekry het, kan u in die hospitaal opgeneem word vir observasie.

Simptome soos lae bloeddruk, hoë bloedsuiker-vlakke en stadige hartklop sal met toepaslike metodes behandel word.

As u vergeet om ADCO ZILDEM SR te gebruik
Moenie ’n dubbel-dosis neem om op te maak vir vergete individuele dosisse nie.

As u gebruik van ADCO ZILDEM SR staak
Praat met u dokter voordat u gebruik van ADCO ZILDEM SR staak.
Vra u dokter, apteker of verpleegster as u enige verdere vrae oor die gebruik van hierdie medisyne het.

4. Moontlike newe-effekte
ADCO ZILDEM SR kan newe-effekte hê.
Nie alle newe-effekte wat vir ADCO ZILDEM SR aangemeld is word in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u gesondheidsorgverskaffer vir advies as u algemene gesondheid versleg of u enige ander nadelige gevolge tydens gebruik van ADCO ZILDEM SR ervaar.

Staak gebruik van ADCO ZILDEM SR en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal as enige van die volgende gebeur:
- Swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaal moeilik kan maak.
- Uitslag of jeuking.
- Floute.

Hierdie is almal baie ernstige newe-effekte. As u hulle ervaar kan u moontlik ’n ernstige allergiese reaksie vir ADCO ZILDEM SR gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik as u enige van die volgende opmerk:
Gereelde newe-effekte:
- Duiseligheid
- Hoofpyn
- Eerstegraadse, tweedegraadse of derdegraadse atrioventrikulêre blokkasie (hartritme-versteurings)
- Bondelvertakkingblokkasie (’n toestand waar daar ’n vertraging of blokkasie langs die pad wat die elektriese impuls beweeg om die hart te laat klop is)
- Hartkloppings (’n geweldige hartklop wat vinnig of onreëlmatig kan wees)
- Blosing (rooiheid van die vel)
- Hardlywigheid
- Slegte spysvertering
- Naarheid
- Gastriese ongemak (abdominale pyn)
- Eriteem (rooiheid van die vel)

- Perifere edeem (swelling, veral van die enkels en voete, as gevolg van opbou van vloeistof)
- Algemene siek gevoel

Minder gereelde newe-effekte:
- Senuweeagtigheid
- Insomnia (slapeloosheid)
- Bradikardie (stadige hartklop)
- Ortostatiese hipotensie (duiseligheid wanneer u opstaan of regop sit as gevolg van ’n daling van bloeddruk)
- Bronchospasma (uitermatige en verlengde sametrekking van die lugwegspiere wat asemhaling bemoeilik), insluitend verergering van asma
- Droë mond
- Braking
- Diarree
- Toename van sekere lewer-ensiemvlakke soos AST, ALT, LDH en ALP

Newe-effekte van onbekende gereeldheid:
- Trombositopenie (lae vlakke van bloedplaatjies)
- Hiperglukemie (hoë bloedsuikervlakke)
- Gemoedsveranderinge, insluitend depressie
- Aanmelding van hiperaktiwiteit (verstrooid wees, nie in staat om te konsentreer nie, aggressie, ens.), somtyds met psigiatriese simptome verbind
- Ekstrapiramidale sindroom (bewing, spierspasma of bewegingsversteurings)
- Verwarring
- Geneesmiddel-geïnduseerde Parkinsonisme (bewing, spierstyfheid, stadige beweging, versteurde balans en koördinasie, ens.)
- Kongestiewe hartversaking (wanneer die hart nie die bloed behoorlik pomp nie) of hartaanval
- Sinoatriale blokkasie en sinus arrestasie (hartritme probleme waar die hart te stadig klop, of hartklop onderbreek word of selfs stop)
- Enkel-edeem (swelling van die enkels as gevolg van opbou van vloeistof); kan meer gereeld by bejaardes voorkom
- Vaskulitis (inflammasie van die bloedvate), insluitend leukositolkastiese vaskulitis (inflammasie van die klein bloedselle)
- Sooibrand
- Gingivale hiperplasie (oormatige groei van die tandvleis-weefsel)
- Inflammasie van die lewer
- Uitslag
- Fotosensitiwiteit (sonbrandagtige reaksies na blootstelling aan lig), insluitend lichenoïede keratose (’n nie-kwaadaardige velletsel wat as ’n klein grys-bruin plaak of papil en mees algemeen op die bors of boonste ledemate voorkom)

- Angioneurotiese edeem (vinnige swelling onder die vel)
- Veelvuldige eriteem (’n velreaksie gekenmerk deur teikenvormige letsels)
- Stevens-Johnson sindroom (lewensbedreigende reaksie met griepagtige simptome en pynlike uitslag) en toksiese epidermale nekrolise (lewensbedreigende toestand gekenmerk deur oormatige afskilfering van die vel)
- Sweet
- Afskilferende dermatitis (rooiheid en skilfering van die vel)
- Eksantematiese pustulose (klein etter-gevulde kolle op die vel en uitslag)
- Hiperpigmentasie (verdonkerde kolle of areas op die vel)
- Deskwamatiewe eriteem (afskilfering van die vel) of sonder koors
- ’n Toestand waar die liggaam se verdedigingstelsel normale weefsel aanval wat simptome soos geswelde gewrigte, moegheid en uitslae (genaamd ‘lupus-agtige sindroom’).
- Ginekomastie (abnormale vergroting van borste by mans)
- Toename van sekere ensieme in die liggaam

Stel u dokter of apteker in kennis as u enige newe-effekte wat nie in hierdie voubiljet genoem word nie ervaar.

Aanmelding van newe-effekte
Praat met u dokter of apteker as u newe-effekte ervaar. U kan newe-effekte ook by SAHPRA aanmeld via die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) gevind by SAHPRA se webwerf. Deur newe-effekte aan te meld kan u help met meer inligting oor die veiligheid van ADCO ZILDEM SR.

5. Hoe om ADCO ZILDEM SR te bêre

- Bêre alle medisynes buite bereik van kinders.
- Bêre in ’n koel droë plek teen of laer as 25 °C.
- Hou die stulpverpakkings in die buitenste kartondosie tot dit gebruik moet word.
- Moenie na die vervaldatum wat op die kartondosie gedruk is gebruik nie.
- Gee alle ongebruikte medisyne aan u apteker terug.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van die pak en ander inligting

Wat ADCO ZILDEM SR bevat
Die aktiewe bestanddeel is diltiazem.
ADCO ZILDEM 180 SR: Elke volgehoue vrystelling kapsule bevat 180 mg diltiazemhidrochloried.
ADCO ZILDEM 240 SR: Elke volgehoue vrystelling kapsule bevat 240 mg diltiazemhidrochloried.

Die ander bestanddele is eritrosien (E127), etielsellulose, gelatien, indigo karmyn (E132), povidoon K 30, skulp, suikersfere, talk, titaandioksied (E171).

Hoe ADCO ZILDEM SR lyk en inhoud van die pak
Harde gelatien kapsules.
ADCO ZILDEM 180 SR: Grootte 1 harde gelatien kapsules, natuurlike deurskynende doppie en pienk romp met wit-grys to liggeel korrels gevul.
ADCO ZILDEM 240 SR: Grootte 0 harde gelatien kapsules, natuurlike deurskynende doppie en rooi ondeursigtige romp met wit-grys tot liggeel korrels gevul.

ADCO ZILDEM SR kapsules word in PVC/PVDC stulpverpakkings op aluminiumfoelie verpak in individuele kartondosies, in stroke van 20 kapsules.
Pak groottes van 30 en 100 kapsules.
Nie alle pakgroottes word noodwendig bemark nie.

Houer van Registrasiesertifikaat
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Registrasienommers
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ADCO ZILDEM 240 SR: 30/7.1/0184

Namibië:

ADCO ZILDEM 180 SR: 05/7.1/0274 **NS2**
ADCO ZILDEM 240 SR: 05/7.1/0275 **NS2**

adcock ingram

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