SCHEDULING STATUS **S3**
PROPRIETARY NAMES (AND DOSAGE FORM)
ABECARD 8™ (tablets)
ABECARD 16™ (tablets)
ABECARD 32™ (tablets)
COMPOSITION
ABECARD 8: Each tablet contains 8 mg candesartan cilexetil
ABECARD 16: Each tablet contains 16 mg candesartan cilexetil
ABECARD 32: Each tablet contains 32 mg candesartan cilexetil
Contains sugar (lactose monohydrate).
The other ingredients are: croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, maize starch, triethyl citrate.
PHARMACOLOGICAL CLASSIFICATION
A 7.1.3 Other hypotensives
PHARMACOLOGICAL ACTION
Pharmacodynamic properties
Candesartan is a nonpeptide angiotensin II receptor antagonist that selectively blocks the binding of angiotensin II to the AT_1 receptors. Angiotensin II stimulates the adrenal cortex to synthesise and secrete aldosterone, which decreases the excretion of sodium and increases the excretion of potassium. Angiotensin II also acts as a vasoconstrictor in vascular smooth muscle. By blocking the binding of angiotensin II to the AT_1 receptors, candesartan causes vasodilation and decreases the effects of aldosterone. The antagonism of the AT_1 receptors results in dose-related increases in plasma renin levels, angiotensin I and II levels, and a decrease in plasma aldosterone concentration.
Hypertension
Antihypertensive action is caused by the decreased systemic peripheral resistance. The heart-rate, stroke volume and cardiac output will not be affected by candesartan. Candesartan increases renal blood flow and either has no effect on, or increases glomerular filtration rate while renal vascular resistance and filtration fractions are reduced.
Heart failure
Candesartan decreases pulmonary capillary wedge pressure, systemic vascular resistance and aldosterone levels. Candesartan increases plasma renin activity and angiotensin II concentration.
Pharmacokinetic properties
Absorption and distribution
Candesartan cilexetil is an inactive ester prodrug that is completely hydrolysed to the active form, candesartan, during absorption from the gastrointestinal tract. Peak plasma levels are obtained 3 to 4 hours after oral administration. Candesartan is not affected by food. Candesartan is highly plasma-protein bound (more than 99 %). The volume of distribution of candesartan is 0,1 litres/kg. The candesartan serum concentration increases linearly with increasing doses in the therapeutic dose range.
Metabolism and elimination
The terminal elimination half-life is approximately 9 hours. Elimination after oral administration:
Renal – 33 %; Faecal – 67 %
Candesartan is not removable by haemodialysis.
Elimination of candesartan is primarily as unchanged substance in the urine and, by the biliary route, in the faeces. Minor hepatic metabolism of candesartan occurs by O-deethylation to form an inactive metabolite.
Plasma clearance is about 0,37 mℓ/min per kg. Renal clearance is 0,19 mℓ/min per kg.
Pharmacokinetics in special populations
Elderly patients (65 years and older)
In elderly patients the C_{max} and AUC of candesartan are respectively increased by approximately 50 % and 80 %, compared with young adults.
Renal impairment
In patients with mild (creatinine clearance 60-90 mℓ/min), moderate (creatinine clearance 30-60 mℓ/min) and severe (creatinine clearance 15-30 mℓ/min) renal impairment, the C_{max} and AUC of candesartan increased during repeated dosing. In patients with severe renal impairment both the $t_{1/2}$ and AUC of candesartan were approximately double those of persons with normal renal function. No information is available on patients with more severe renal failure, i.e. creatinine clearance below 15 mℓ/min.
Hepatic impairment
A significant increase in the mean AUC of candesartan of respectively 30 % and 145 % was observed in patients with mild hepatic impairment and patients with moderate to severe hepatic impairment. No data are available on patients with cholestasis or severe hepatic impairment.
INDICATIONS
ABECARD is indicated for mild to moderate hypertension. It may either be given as monotherapy, or for enhanced efficacy, in combination with other antihypertensive agents such as thiazide diuretics and dihydropyridine calcium antagonists.
Heart failure: Treatment with **ABECARD** can reduce mortality, reduce hospitalisation due to heart failure and improve symptoms in patients with impaired left ventricular systolic function (LVEF ≤ 40 %).
CONTRA-INDICATIONS
- Hypersensitivity to any of the components of **ABECARD**.
- A history of angioedema related to previous therapy with ACE-inhibitors or angiotensin receptor blockers (ARBs): These patients must never again be given these medicines.
- Hereditary or idiopathic angioedema.
- Hypertrophic obstructive cardiomyopathy (HOCM).
- Severe renal function impairment (creatinine clearance less than 30 mℓ/min).
- Bilateral renal artery stenosis.
- Renal artery stenosis in patients with a single kidney.
- Aortic stenosis.
- Concomitant therapy with potassium-sparing diuretics such as spironolactone, triamterene, amiloride (see **INTERACTIONS**).
- Porphyria.
- Lithium therapy: Concomitant administration with **ABECARD** may lead to toxic blood concentrations of lithium.
- Pregnancy and lactation (see **PREGNANCY AND LACTATION**).
- Safety and efficacy have not been established in children.

WARNINGS AND SPECIAL PRECAUTIONS
Warnings
Should a woman become pregnant while taking ABECARD, the treatment should be stopped promptly and switched to a different class of antihypertensive medicine (see CONTRA-INDICATIONS and PREGNANCY AND LACTATION).
Special precautions
General
Treatment with medicines that affect the renin-angiotensin-aldosterone system has been associated with acute hypotension, uraemia, oliguria or acute renal failure in patients whose vascular tone and renal function mainly depend on the activity of this system (e.g. patients with severe congestive heart failure or underlying renal disease, including renal artery stenosis).
Excessive blood pressure decrease in patients with ischaemic heart disease or ischaemic cerebrovascular disease could result in myocardial infarction or stroke.
Hypotension
Hypotension may occur during treatment with **ABECARD** in heart failure patients and in hypertensive patients with intravascular volume depletion. Caution should be observed when initiating therapy and correction of hypovolaemia should be attempted; a lower dose may also be required (see **DOSAGE AND DIRECTIONS FOR USE**).
Renal artery stenosis
Increases in serum creatinine or blood urea have occurred in patients with unilateral or bilateral renal artery stenosis or stenosis of the artery to a solitary kidney (see **CONTRA-INDICATIONS**).
Renal impairment
Changes in renal function may be anticipated in susceptible patients treated with **ABECARD**. Periodic monitoring of serum potassium and creatinine levels is recommended in hypertensive patients with renal impairment.
Monitoring of patients with heart failure should include periodic assessments of renal function, especially in elderly patients and patients with impaired renal function. During dose titration of **ABECARD**, monitoring of serum creatinine and potassium is recommended.
There is no experience regarding the administration of **ABECARD** in patients with a recent kidney transplant.
Hepatic impairment
For patients with moderate hepatic impairment, consideration should be given to initiation of **ABECARD** at a lower dose. No initial dosage adjustment is necessary in patients with mild hepatic impairment (see **DOSAGE AND DIRECTIONS FOR USE**). No information is available on the use of **ABECARD** in patients with severe hepatic function impairment.
Hyperkalaemia
The concurrent use of **ABECARD** with potassium-sparing diuretics, salt substitutes, potassium supplements or any medicine that may increase potassium in patients, may lead to increases in serum potassium in hypertensive patients.
Since hyperkalaemia may occur, serum potassium concentrations should be monitored in patients with heart failure. Concomitant administration with ACE-inhibitors or a potassium-sparing diuretic is not recommended (see **CONTRA-INDICATIONS** and **INTERACTIONS**).
Heart failure
Caution should be observed when initiating **ABECARD** in heart failure patients; these patients commonly have some reduction in blood pressure when given **ABECARD** and may require a temporary reduction in dose and/or diuretic and volume repletion.
Anaesthesia and surgery
Due to blockade of the renin-angiotensin system patients may experience hypotension during anaesthesia and surgery when receiving **ABECARD**. In case of severe hypotension it may be necessary to administer intravenous fluids and/or vasopressors.
Lactose
ABECARD contains lactose.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take **ABECARD**.
Effects on ability to drive and use machines
The effect of **ABECARD** on the ability to drive and use machines has not been studied. When driving vehicles or operating machines, it should be taken into account that dizziness or weakness may occur during treatment.
INTERACTIONS
Combinations containing any of the following medications, depending on the amount present, may also interact with **ABECARD**
- Other antihypertensives. The antihypertensive effect of **ABECARD** may be enhanced.
- Potassium-sparing diuretics such as spironolactone, potassium supplements and salt substitutes containing potassium may increase potassium levels. In heart failure patients treated with **ABECARD**, hyperkalaemia may occur especially when taken concomitantly with these medicines (see **CONTRA-INDICATIONS**).
- Diuretics. Concurrent use with **ABECARD** may have additive hypotensive effects.
- Lithium. Serum lithium level increases and toxicity have been reported with concomitant use (see **CONTRA-INDICATIONS**).

PREGNANCY AND LACTATION
Pregnancy (see **CONTRA-INDICATIONS**)
Safety in pregnancy and lactation has not been established (see **CONTRA-INDICATIONS**).
When pregnancy is planned or confirmed **ABECARD** should be discontinued. Medicines affecting the renin-angiotensin system, such as **ABECARD**, can cause embryonic toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women.
Women of childbearing age should ensure effective contraception.
Lactation
It is not known whether **ABECARD** is distributed into human breast milk. **ABECARD** is distributed into the milk of lactating rats. Because of the potential for adverse effects on the nursing infant, breastfeeding should be discontinued if the use of **ABECARD** is considered essential.
DOSAGE AND DIRECTIONS FOR USE
Dosage in hypertension
The recommended initial dose of **ABECARD** is 8 mg once daily. The usual maintenance dose is 8 to 16 mg once daily.
The maximum antihypertensive effect is attained within 4 weeks. In some patients whose blood pressure is not adequately controlled, the dose can be increased to a maximum of 32 mg once daily.
Concomitant therapy
ABECARD may be used as monotherapy or if necessary, concomitantly with other antihypertensive agents, such as thiazide diuretics and dihydropyridine calcium antagonists, e.g. amlodipine.
Special patient populations
Use in elderly (65 years and older)
No initial dosage adjustment is required for elderly patients with normal renal and hepatic function.
Use in children
The safety and efficacy of **ABECARD** have not been established in children.
Use in impaired renal function
No initial dose adjustment is necessary for patients with mild to moderate renal impairment (i.e. creatinine clearance ≥ 30 mℓ/min per 1,73 m^2 BSA). **ABECARD** is contra-indicated in patients with severe renal impairment (< 15-30 mℓ/min per 1,73 m^2 BSA).
Use in hepatic impairment
No initial dosage adjustment is required in patients with mild to moderate hepatic impairment (see **WARNINGS AND SPECIAL PRECAUTIONS**).
There is no experience available in patients with severe hepatic impairment and/or cholestasis (see **CONTRA-INDICATIONS**).
Use in black patients
The antihypertensive effect of **ABECARD** may be less in black than non-black (Caucasian, Asian and other) patients. Consequently, up-titration of **ABECARD** and concomitant therapy (such as thiazide diuretics) may be more frequently needed for blood pressure control in black than non-black patients.
Dosage in heart failure
The usual recommended initial dose of **ABECARD** is 4 mg once daily with a target dose of 32 mg once daily. This is achieved by doubling the dose at approximately 2 week intervals, as tolerated by the patient (see **WARNINGS AND SPECIAL PRECAUTIONS**).
Concomitant therapy
ABECARD may be given concomitantly with other cardiac failure treatment, such as ACE-inhibitors, beta-blockers, diuretics and digitalis or a combination of these medicinal products.
Special patient populations
Elderly (65 years or older)
No initial dose adjustment is necessary for elderly patients with normal renal and hepatic function.
Children
The safety and efficacy of **ABECARD** have not been established in children.
Directions for use
ABECARD may be taken with or without food.
SIDE EFFECTS
The following side effects may occur
Infections and infestations
Frequent: Respiratory infections.
Blood and lymphatic system disorders
Less frequent: Leukopenia, neutropenia, agranulocytosis, thrombocytopenia.
Immune system disorders
Less frequent: Angioedema.
Metabolism and nutrition disorders
Frequent: Hyperkalaemia.
Less frequent: Hyponatraemia.
Nervous system disorders
Frequent: Headache, dizziness/vertigo.
Cardiac disorders
Less frequent: Angina pectoris, myocardial infarction.
Vascular disorders
Frequent: Hypotension.
Respiratory, thoracic and mediastinal disorders
Less frequent: Pharyngitis, rhinitis, upper respiratory tract infection, cough.
Gastrointestinal disorders
Less frequent: Nausea.
Hepato-biliary disorders
Less frequent: Abnormal hepatic function, increased liver enzymes, hepatitis.
Skin and subcutaneous tissue disorders
Less frequent: Urticaria, pruritus, rash.
Musculoskeletal and connective tissue disorders
Less frequent: Hyperuricaemia or gout, back pain, myalgia, arthralgia.
Renal and urinary disorders
Frequent: Impaired renal function.
Less frequent: Renal failure in susceptible patients (see **WARNINGS & SPECIAL PRECAUTIONS**).
Investigations
Less frequent: Increases in creatinine, urea and potassium. Decreases in haemoglobin and hematocrit values. Raised liver enzyme values.
KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
The symptoms of an overdosage of **ABECARD** would be dizziness, hypotension and tachycardia. Bradycardia could occur from parasympathetic (vagal) stimulation. If symptomatic hypotension should occur, supportive treatment should be instituted. **ABECARD** can NOT be removed by haemodialysis.
IDENTIFICATION
ABECARD 8: Round, biconvex, approximately 8 mm in diameter, white to off-white tablets with a breaking notch on one side and embossed on the same side with "C8".
ABECARD 16: Round, biconvex, approximately 8 mm in diameter, white to off-white tablets with a breaking notch on one side and embossed on the same side with "C16".
ABECARD 32: Round, biconvex, approximately 10,5 mm in diameter, white to off-white tablets with a breaking notch on one side and embossed on the same side with "C32".
PRESENTATION
Packs of 28 or 30 tablets packed in transparent PVC/PVDC/Aluminium blisters in a cardboard carton.
STORAGE INSTRUCTIONS
Store in the original packaging (blisters in the carton) at or below 25 °C.
KEEP MEDICINE OUT OF THE REACH OF CHILDREN.
REGISTRATION NUMBERS
ABECARD 8: 46/7.1.3/0231; **ABECARD 16**: 46/7.1.3/0232; **ABECARD 32**: 46/7.1.3/0233
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION
Lasara Traders (Pty) Ltd
Suite C, Rubenstein Ridge, 617 Rubenstein Drive,
Moreleta Park, 0181
MARKETED BY
Forrester Pharma (Pty) Ltd
13 Pasita Street, Rosen Heights, Rosen Park, Bellville, 7530
DATE OF PUBLICATION OF THIS PACKAGE INSERT
11 June 2015

LI0033/15A

PATIENT INFORMATION LEAFLET
SCHEDULING STATUS **S3**
PROPRIETARY NAMES (AND DOSAGE FORM)
ABECARD 8 ™ (tablets)
ABECARD 16 ™ (tablets)
ABECARD 32 ™ (tablets)
Read this leaflet carefully before you start taking ABECARD
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ABECARD** 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 ABECARD CONTAINS
- The active ingredient is candesartan cilexetil.
  ABECARD 8: Each tablet contains 8 mg candesartan cilexetil
  ABECARD 16: Each tablet contains 16 mg candesartan cilexetil
  ABECARD 32: Each tablet contains 32 mg candesartan cilexetil
- Contains a sugar (lactose).
- The other ingredients are: croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, maize starch, triethyl citrate.

WHAT ABECARD IS USED FOR
ABECARD belongs to a class of medicines called angiotensin II receptor antagonists (ARBs). It keeps blood vessels from narrowing, thereby lowering blood pressure and improving blood flow.
ABECARD is used to:
- treat mild or moderate high blood pressure (hypertension); or for
- heart failure. Heart failure is a condition where the pumping action of the heart is not good enough. This can result in a reduced flow of blood from the heart.

BEFORE YOU TAKE ABECARD
Do not take ABECARD
- if you are hypersensitive (allergic) to the active ingredient in **ABECARD**, or to any of the other ingredients in the tablet (see also **WHAT ABECARD CONTAINS**);
- if you are pregnant, planning to be pregnant, or breastfeeding (see **Pregnancy and breastfeeding** below);
- if you previously had angioedema with angiotensin-converting enzyme (ACE) inhibitors or ARBs, or have had these symptoms in any other circumstances. Some signs may have been swelling of the face, tongue or throat, wheezing, skin rashes, intense itching, dizziness or fainting;
- if you have a history of idiopathic angioedema. This is a skin reaction similar to hives and includes swelling of the skin;
- if you have a heart disorder in which the flow of blood out of the heart is blocked due to the walls of the ventricles (lower heart chambers) thickening and becoming stiff;
- if you have serious kidney problems;
- if you have a narrowing of the aortic valve opening between the left ventricle (left lower heart chamber) and the aorta (the main artery leading away from the heart);
- if you have narrowing or blockage of the blood vessels to both kidneys or to a single working kidney;
- if you are taking water tablets (diuretics) such as spironolactone, amiloride or triamterene that cause your body to hold potassium;
- if you have porphyria (an inherited disorder in the metabolism of the red blood cell pigment, affecting the skin or nervous system); or
- if you are on lithium therapy (which may be used for mental disorders such as mania).

ABECARD tablets should not be given to children.
Take special care with ABECARD
Tell your doctor before taking ABECARD if you
- plan to be pregnant or if you breastfeed your baby (see **Do not take ABECARD** above and also the important information under **Pregnancy and breastfeeding**);
- become dehydrated (volume depleted), for example, if you were vomiting, or had diarrhoea or heavy sweating, or if you follow a salt restricted diet or use diuretics;
- have kidney disease;
- have liver disease;
- have higher-than-normal levels of potassium in the blood or if you are taking medicines that may increase potassium;
- have heart failure, a condition in which the heart cannot pump enough blood to meet the body's needs;
- are going to have an operation and going to receive anaesthetics (medicines that cause a loss of consciousness during operations); or if you
- are allergic to lactose (see also **Important information on some of the ingredients of ABECARD**).

Taking ABECARD with food and drink
ABECARD can be taken with or without food.
Avoid drinking alcohol. Drinking alcohol with **ABECARD** may further lower your blood pressure and may make you feel dizzy or lightheaded.
Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ABECARD.
You should not take ABECARD
- if you are pregnant, planning to become pregnant or if you suspect you are pregnant, as **ABECARD** may affect your unborn baby;
- if you are breastfeeding your baby.

Please note
You should immediately inform your doctor, pharmacist or healthcare professional that you are taking **ABECARD** if you suspect that you are pregnant. If it is confirmed that you are pregnant, you should stop taking **ABECARD** as soon as possible. Your doctor will prescribe another medicine to control your blood pressure.
Women of childbearing age should ensure effective contraception.
Driving and using machinery
ABECARD may make you feel dizzy or lightheaded.
Do not drive, operate machinery, handle tools or do anything else that could be dangerous until you know how you react on **ABECARD**.
Important information about some of the ingredients of ABECARD
ABECARD contains lactose (milk sugar). If you have a rare hereditary intolerance to sugars inform your doctor; you should not take **ABECARD**.
Taking other medicines with ABECARD
Always tell your doctor or healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).
Make especially sure your doctor knows that you take
- lithium (see **Do not take ABECARD** above);
- other medicines to lower your blood pressure, as they may further reduce your blood pressure;
- potassium supplements, potassium-containing salt substitutes and potassium-sparing diuretics (e.g. spironolactone, triamterene or amiloride);
- diuretics ("water tablets").

Before you begin taking any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using **ABECARD**, check with your doctor, healthcare professional or pharmacist.
HOW TO TAKE ABECARD
Do not share medicines prescribed for you with any other person.
Always take **ABECARD** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is
High blood pressure
The usual starting dose is 1 x **ABECARD** 8 mg tablet once daily. The usual maintenance dose is 1 x **ABECARD** 8 mg or 1 x **ABECARD** 16 mg tablet once daily for most patients.
Your doctor may prescribe up to 32 mg once daily in some cases.
It may take about 4 weeks of using **ABECARD** before your blood pressure is under control. Continue taking your medication as prescribed by your doctor, even if you feel fine. High blood pressure often has no symptoms.
Heart failure
The usual starting dose is 4 mg (½ tablet of the **ABECARD** 8 mg) once daily.
Your doctor may gradually increase your dose to 32 mg once a day to help to control your heart failure.
ABECARD may be taken with or without food, with some water. Take your **ABECARD** at the same time each day.
Use in black patients
The blood pressure lowering effect may be less in black than non-black (Caucasian, Asian and other) patients. Your doctor may add additional medication such as water tablets.
Use in children
ABECARD is not suitable for use in children.
Duration of treatment
Your doctor will tell you how long your treatment with **ABECARD** will last.
Do not stop treatment early because your blood pressure will no longer be controlled.
If you have the impression that the effect of **ABECARD** is too strong or too weak, talk to your doctor or pharmacist.
If you take more ABECARD than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.
Some of the symptoms of overdose are low blood pressure (feeling dizzy, lightheaded, and sick) and changes in the heartbeat (increased heartbeat or possibly decreased heartbeat).
If you forget to take/missed a dose of ABECARD
It is important to take your medicine every day. However, if you forget to take one or more doses, take another as soon as you remember and then go on as prescribed on a normal daily dose. Do not take a double dose to make up for forgotten individual doses.
POSSIBLE SIDE EFFECTS
ABECARD can have side effects.
Not all side effects reported for **ABECARD** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ABECARD**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking ABECARD tablets and tell your doctor immediately or go to the casualty department at your nearest hospital
- hives, severe stomach pain, difficulty in breathing, swelling of your face, lips, tongue, or throat, dizziness or fainting, unusually fast or irregular heartbeat. These could be signs of angioedema.

If you have these symptoms, you may have had a very serious allergic reaction to **ABECARD**. You may need urgent medical attention or hospitalisation.
Tell your doctor IMMEDIATELY or go to the casualty department at your nearest hospital if you notice any of the following
- heart attack or angina pectoris (pressure, squeezing, burning, or tightness in the chest. The pain or discomfort usually starts behind the breastbone);
- signs of liver inflammation, such as fever, nausea, yellowing of the skin and eyes;
- less urine than is normal for you.

These are all serious side effects. You may need urgent medical attention.
Tell your doctor if you notice any of the following
The following side effects may occur frequently
- signs of recurrent respiratory infections such as sinus disorders;
- high potassium concentration in the blood (hyperkalaemia). See your doctor if you feel sick, tired, have weak muscles and tingling sensations. He/she may order blood tests to know if you have too much potassium in your blood;
- headache, dizziness or a feeling of spinning;
- too low blood pressure (some signs may be light-headedness, dizziness and fainting).

The following side effects occur less frequently
- reduced number of white blood cells (you may notice that you frequently get infections);
- easy or excessive bruising due to a low blood platelet count;
- back pain, muscle pain, painful joints or gout (some signs may be a feeling of warmth, pain, swelling and extreme tenderness in a joint, usually a big toe joint);
- too low sodium salt concentration in your blood (some signs may be feeling sick, having a headache and muscle spasms and cramps. Your doctor may want to order blood tests to see if you have this deficiency);
- cough, fever or sore throat, stuffy nose;
- nausea (feeling sick);
- skin rash.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
STORAGE AND DISPOSING OF ABECARD
Keep out of reach of children.
Store in the original package (in the blisters in the carton) at or below 25 ˚C.
Do not store your medicines in the bathroom.
Do not use **ABECARD** after the expiry date printed on the carton or blister.
Return all expired or unused medicine to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).
PRESENTATION OF ABECARD
Packs of 28 or 30 tablets packed in transparent PVC/PVDC/Aluminium blisters in a cardboard carton.
IDENTIFICATION OF ABECARD
ABECARD 8: Round, biconvex, approximately 8 mm in diameter, white to off-white tablets with a breaking notch on one side and embossed on the same side with "C8".
ABECARD 16: Round, biconvex, approximately 8 mm in diameter, white to off-white tablets with a breaking notch on one side and embossed on the same side with "C16".
ABECARD 32: Round, biconvex, approximately 10,5 mm in diameter, white to off-white tablets with a breaking notch on one side and embossed on the same side with "C32".
REGISTRATION NUMBERS
ABECARD 8: 46/7.1.3/0231; **ABECARD 16**: 46/7.1.3/0232; **ABECARD 32**: 46/7.1.3/0233
NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION
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DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET
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LI0032/15A

SKEDULERINGSTATUS S3
HANDELSNAME (EN DOSEERVORM)
ABECARD 8™ (tablette)
ABECARD 16™ (tablette)
ABECARD 32™ (tablette)
SAMESTELLING
ABECARD 8: Elke tablet bevat 8 mg kandesartaansileksetil
ABECARD 16: Elke tablet bevat 16 mg kandesartaansileksetil
ABECARD 32: Elke tablet bevat 32 mg kandesartaansileksetil
Bevat suiker (laktosemonohidraat).
Die ander bestanddele is: natrium-kroskarmellose, hidroksiepropielsellulose, magnesiumstearaat, mieliestysel, triëtielsitraat.
FARMAKOLOGIESE KLASSIFIKASIE
A 7.1.3 Ander hipotensiemiddels.
FARMAKOLOGIESE WERKING
Farmakodinamiese eienskappe
Kandesartaan is 'n nie-peptied angiotensien-II reseptorantagonis wat die binding van angiotensien II aan die AT_1-reseptore selektief blokkeer. Angiotensien II stimuleer die bynierkorteks om aldosteroon te vervaardig en af te skei, waardeur die uitskeiding van natrium verminder word en dié van kalium verhoog word. Angiotensien II het ook 'n vasokonstriktiewe uitwerking op vaskulêre gladdespier. Deur die binding van angiotensien II by die AT_1-reseptore te blokkeer, veroorsaak kandesartaan vasodilatasie en verminder die effekte van aldosteroon. Die antagonisme van die AT_1-reseptore lei tot dosisverwante stygings in plasmarenienvlakke, angiotensien I- en II-vlakke, en 'n afname in plasma-aldosteroonkonsentrasie.
Hipertensie
Die antihipertensiewe werking word teweeg gebring deur die afname in perifere weerstand. Die harttempo, slagvolume en hartomset sal nie deur kandesartaan beïnvloed word nie. Kandesartaan verhoog renale bloedvloei en het óf geen effek daarop nie, of dit verhoog die glomerulêre filtrasietempo terwyl die renale vaskulêre weerstand en filtrasiegedeelte verminder.
Hartversaking
Kandesartaan verminder pulmonale kapillêre wig-druk, sistemiese vaskulêre weerstand en aldosteroonvlakke. Kandesartaan verhoog die plasmarenienaktiwiteit en angiotensien-II konsentrasie.
Farmakokinetiese eienskappe
Absorpsie en verspreiding
Kandesartaansileksetil is 'n onaktiewe ester-progeneesmiddel wat tydens absorpsie uit die spysverteringskanaal volledig tot die aktiewe vorm, kandesartaan, gehidroliseer word. Piekplasmavlakke word 3 tot 4 uur na orale toediening bereik. Kandesartaan word nie deur voedsel beïnvloed nie. Kandesartaan is hoogs gebonde aan plasmaproteïene (meer as 99 %). Die oënskynlike verspreidingsvolume van kandesartaan is 0,1 liter/kg. Die serumkonsentrasie van kandesartaan neem lineêr toe met toenemende dosisse binne die bestek van die terapeutiese dosis.
Metabolisme en uitskeiding
Die terminale eliminasiehalfleeftyd is ongeveer 9 uur.
Eliminasie na mondelike toediening:
Renaal - 33 %; Fekaal - 67 %
Kandesartaan kan nie deur hemodialise verwyder word nie. Uitskeiding van kandesartaan geskied hoofsaaklik as die onveranderde stof in die urine en, via die gal, in die feses. Geringe hepatiese metabolisme van kandesartaan geskied deur O-deëtilering om 'n onaktiewe metaboliet te vorm. Plasma-opruiming is ongeveer 0,37 mℓ/min per kg. Renale opruiming is 0,19 mℓ/min per kg.
Farmakokinetika in spesiale populasiegroepe
Bejaarde pasiënte (65 jaar en ouer)
By bejaarde pasiënte neem die piekplasmakonsentrasie en AOK van kandesartaan onderskeidelik toe met ongeveer 50 % en 80 %, in vergelyking met jong volwassenes.
Ingekorte nierfunksie
By pasiënte met ligte (kreatinienopruiming 60-90 ml/min), matige (kreatinienopruiming 30-60 ml/min) en ernstige (kreatinienopruiming 15-30 ml/min) renale inkorting het die piekplasmakonsentrasies en AOK van kandesartaan met herhaalde dosisse toegeneem. By pasiënte met ernstig verswakte nierfunksie was beide die $t_{1/2}$ en die AOK van kandesartaan ongeveer dubbel dié van persone met normale nierfunksie. Geen inligting is beskikbaar oor pasiënte met meer ernstige nierversaking nie, d.i. kreatinienopruiming onder 15 ml/min.
Lewerontoereikendheid
'n Beduidende toename in die gemiddelde AOK van kandesartaan van onderskeidelik 30 % en 145 % is waargeneem by pasiënte met ligte ingekorte lewerfunksie en pasiënte met 'n matige-tot-ernstige lewerfunksie. Daar is geen beskikbare gegewens oor pasiënte met cholestase of ernstige lewerinkorting nie.
AANWYSINGS
ABECARD is aangedui vir ligte tot matige hipertensie. Dit kan óf gegee word as 'n monoterapie óf vir beter doeltreffendheid in kombinasie met ander antihipertensiewe geneesmiddels soos tiasieddiuretika en dihidropiridien kalsiumkanaalblokkers. Hartversaking: Behandeling met **ABECARD** kan mortaliteit en hospitalisasie weens hartversaking verminder en simptome by pasiënte met verswakte linker-ventrikulêre sistoliese funksie (LVEF ≤ 40 %) verbeter.
TEENAANWYSINGS
- Hipersensitiwiteit vir enige van die komponente van **ABECARD**.
- 'n Geskiedenis van angio-edeem vanweë vorige behandeling met AOE-remmers of angiotensienreseptorblokkers (ARBs): Hierdie pasiënte moet nooit weer hierdie medisyne gegee word nie.
- Oorgeërfde of idiopatiese angio-edeem.
- Hipertrofiese obstruktiewe kardiomiopatie (HOKM).
- Ernstig verswakte nierfunksie (kreatinienopruiming minder as 30 ml/min).
- Bilaterale nieraarstenose.
- Nieraarstenose by pasiënte met 'n enkele nier.
- Stenose van die aorta.
- Kombinasiebehandeling met kaliumsparende diuretika soos spironolaktoon, triamtereen, amiloried (kyk **INTERAKSIES**).
- Porfirie.
- Litiumbehandeling: Gelyktydige toediening van **ABECARD** kan lei tot 'n toksiese bloedkonsentrasie van litium.
- Swangerskap en laktasie (kyk **SWANGERSKAP EN LAKTASIE**).
- Veiligheid en doeltreffendheid is nie by kinders bepaal nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS
Waarskuwings
Indien 'n vrou swanger raak terwyl sy ABECARD neem, moet die behandeling onmiddellik gestaak word en na 'n ander klas van antihipertensiewe medisyne oorgeskakel word (kyk KONTRA-INDIKASIES en SWANGERSKAP EN BORSVOEDING).
Spesiale voorsorgmaatreëls
Algemeen
Behandeling met medisyne wat die renien-angiotensien-aldosteroon-kaskade beïnvloed is met akute hipotensie, uremie, oligurie of akute nierversaking geassosieer by pasiënte wie se vaskulêre tonus en nierfunksie hoofsaaklik afhang van die aktiwiteit van hierdie stelsel (bv. pasiënte met ernstige kongestiewe hartversaking of onderliggende niersiekte, waaronder nieraarstenose).
Buitensporige afname in bloeddruk by pasiënte met iskemiese hartsiekte of iskemiese serebrovaskulêre siekte kan lei tot miokardiale infarksie of beroerte.
Hipotensie
Hipotensie kan tydens die behandeling met **ABECARD** by pasiënte met hartversaking en by hipertensiewe pasiënte met intravaskulêre volume-uitputting voorkom. Versigtigheid moet uitgeoefen word wanneer die behandeling begin word en daar moet gepoog word om hipovolemie reg te stel; 'n laer dosis kan ook vereis word (kyk **DOSIS EN GEBRUIKSAANWYSINGS**).
Nierslagaarstenose
Toenames in serumkreatinien of bloedureum het by pasiënte met eensydige of bilaterale nierslagaarstenose of stenose van die arterie na 'n enkele nier plaasgevind (kyk **KONTRA-INDIKASIES**).
Ingekorte nierfunksie
Veranderinge in nierfunksie kan verwag word by vatbare pasiënte wat behandel word met **ABECARD**.
Periodieke monitering van serumkalium en -kreatinienvlakke word aanbeveel by hipertensiewe pasiënte met swak nierfunksie. Monitering van pasiënte met hartversaking moet periodieke evaluering van die nierfunksie, veral by bejaarde pasiënte en pasiënte met verswakte nierfunksie, insluit. Monitering van serumkreatinien en -kalium word tydens titrasie van die **ABECARD** dosis aanbeveel. Daar is geen ondervinding van die toediening van **ABECARD** by pasiënte met 'n onlangse nieroorplanting nie.
Lewerontoereikendheid
Dit kan oorweeg word om **ABECARD** by 'n laer dosis te begin by pasiënte met matig verswakte lewerfunksie. Geen aanvanklike dosisaanpassing is nodig by pasiënte met effens verswakte lewerfunksie nie (kyk **DOSIS EN GEBRUIKSAANWYSINGS**). Geen inligting is beskikbaar oor die gebruik van **ABECARD** by pasiënte met ernstig verswakte lewerfunksie nie.
Hiperkalemie
Die gelyktydige gebruik van **ABECARD** met kaliumsparende diuretika, soutplaasvervangers, kaliumaanvullings of enige medisyne wat kalium kan verhoog in pasiënte, kan lei tot 'n toename in serumkalium by hipertensiewe pasiënte. Aangesien hiperkalemie kan voorkom, moet die serumkaliumkonsentrasies gemoniteer word by pasiënte met hartversaking. Gelyktydige toediening met AOE-remmers of 'n kaliumsparende diuretikum word nie aanbeveel nie (kyk **KONTRA-INDIKASIES** en **INTERAKSIES**).
Hartversaking
ABECARD moet met versigtigheid begin word by pasiënte met hartversaking; hierdie pasiënte het gewoonlik 'n ietwat verlaagde bloeddruk as **ABECARD** aan hulle gegee word en hulle kan moontlik 'n tydelike verlaging in dosis en/of 'n diuretikum en volume-aanvulling benodig.
Narkose en chirurgie
Weens blokkade van die renien-angiotensien-sisteem kan pasiënte hipotensie tydens narkose en chirurgie ervaar wanneer hulle **ABECARD** ontvang. In die geval van ernstige hipotensie kan dit nodig wees om binneaarse vloeistowwe en/of vasopressors toe te dien.
Laktose
ABECARD bevat laktose.
Pasiënte met seldsame oorerflike probleme soos galaktose intoleransie, die Lapp-laktasetekort of glukose-galaktose wanabsorpsie moet nie **ABECARD** neem nie.
Effek op die vermoë om te bestuur en masjinerie te gebruik
Die uitwerking van **ABECARD** op die vermoë om te bestuur of masjinerie te hanteer is nie ondersoek nie. Wanneer voertuie bestuur word of masjinerie hanteer word, moet dit in ag geneem word dat duiseligheid of swakheid tydens die behandeling kan voorkom.
INTERAKSIES
Kombinasies van enige van die volgende medisyne, afhangende van die hoeveelhede teenwoordig, kan ook 'n wisselwerking met **ABECARD** uitoefen
- Ander antihipertensiewe middels. Die antihipertensiewe effek van **ABECARD** kan versterk word.
- Kaliumsparende diuretika soos spironolaktoon, kaliumaanvullings en soutplaasvervangers wat kalium bevat, kan kaliumvlakke verhoog. By pasiënte met hartversaking, wat behandel is met **ABECARD**, kan hiperkalemie veral voorkom wanneer dit gelyktydig met hierdie medisynes geneem word (kyk **KONTRA-INDIKASIES**).
- Diuretika. Gelyktydige gebruik met **ABECARD** kan 'n toegevoegde hipotensiewe effek hê.
- Litium. Die serumlitiumvlak styg en toksisiteit is met die gelyktydige gebruik aangemeld (kyk **KONTRA-INDIKASIES**).

SWANGERSKAP EN LAKTASIE
Swangerskap (kyk **KONTRA-INDIKASIES**)
Die veiligheid met swangerskap en laktasie is nie vasgestel nie (kyk **TEENAANWYSINGS**).
Wanneer swangerskap beplan word of bevestig is, moet **ABECARD** gestaak word. Medisyne wat die renien-angiotensien-sisteem affekteer, soos **ABECARD**, kan embrionale toksisiteit, fetale en neonatale morbiditeit en mortaliteit veroorsaak as dit aan swanger vrouens toegedien word. Vrouens in die ouderdomsgroep vir swangerskap moet doeltreffende voorbehoeding verseker.
Laktasie
Dit is nie bekend of **ABECARD** in menslike borsmelk versprei nie. **ABECARD** word in die melk van lakterende rotte versprei. As gevolg van die moontlikheid van 'n negatiewe uitwerking op die suigeling, moet borsvoeding gestaak word indien die gebruik van **ABECARD** as noodsaaklik beskou word.
DOSIS EN GEBRUIKSAANWYSINGS
Dosis by hipertensie
Die aanbevole aanvangsdosis van **ABECARD** is 8 mg een keer daagliks. Vir instandhouding is die gewone dosis 8 tot 16 mg een keer daagliks. Die maksimum antihipertensiewe effek word binne 4 weke bereik. By sommige pasiënte by wie die bloeddruk nie voldoende beheer is nie, kan die dosis tot 'n maksimum van 32 mg een keer daagliks verhoog word.
Gelyktydige behandeling
ABECARD kan óf as 'n monoterapie óf in kombinasie met ander antihipertensiewe middels soos tiasieddiuretika en dihidropiridien kalsiumkanaalblokkers, soos amlodipien, gebruik word.
Spesiale pasiëntpopulasies
Gebruik by bejaarde pasiënte (65 jaar en ouer)
Geen aanvanklike dosisaanpassing is nodig vir bejaarde pasiënte met normale nier- en lewerfunksie nie.
Gebruik by kinders
Die veiligheid en doeltreffendheid van **ABECARD** is nie by kinders bepaal nie.
Gebruik by verswakte nierfunksie
Geen aanvanklike dosisaanpassing is nodig by pasiënte met effens verswakte tot matig verswakte nierfunksie nie (d.w.s. kreatinienopruiming ≥ 30 mℓ/min per 1,73 m^2 LOA). **ABECARD** is ook teenaangedui by pasiënte met erg verswakte niere (< 15-30 mℓ/min per 1,73 m^2 LOA).
Gebruik by verswakte lewerfunksie
Die dosis hoef nie by pasiënte met ligte tot matige swak lewerfunksie aangepas te word nie (kyk **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).
Daar is geen ondervinding in pasiënte met ernstig verswakte lewerfunksie en/of cholestase nie (kyk **KONTRA-INDIKASIES**).
Gebruik by swart pasiënte
Die antihipertensiewe uitwerking van **ABECARD** kan minder wees by swart as by nie-swart (Kaukasiese, Asiatiese en ander) pasiënte. Gevolglik kan opwaartse titrasie van **ABECARD** en gelyktydige behandeling (soos tiasieddiuretika) meer dikwels nodig wees vir bloeddrukbeheer by swart as by nie-swart pasiënte.
Dosis by hartversaking
Die gewone aanbevole aanvangsdosis van **ABECARD** is 4 mg een keer daagliks met 'n teikendosis van 32 mg een keer daagliks. Dit word bereik deur die dosis teen ongeveer 2-weeklikse tussenposes te verdubbel, soos wat die pasiënt dit kan verdra (kyk **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).
Gelyktydige behandeling
ABECARD kan gelyktydig met ander behandelings vir hartversaking, soos AOE-remmers, beta-blokkers, diuretika en digitalis of 'n kombinasie van hierdie medisynes gegee word.
Spesiale pasiëntpopulasies
Bejaardes (65 jaar en ouer)
Geen aanvanklike dosisaanpassing is nodig vir bejaarde pasiënte met normale nier- en lewerfunksie nie.
Kinders
Die veiligheid en doeltreffendheid van **ABECARD** is nie by kinders bepaal nie.
Gebruiksaanwysings
ABECARD kan met of sonder kos geneem word.
NEWE-EFFEKTE
Die volgende newe-effekte kan voorkom
Infeksies en besmettings
Dikwels: Respiratoriese infeksies.
Bloed- en limfstelselversteurings
Minder dikwels: Leukopenie, neutropenie, agranulositose, trombositopenie.
Immuunstelselversteurings
Minder dikwels: Angio-edeem.
Metabolisme en voedingsversteurings
Dikwels: Hiperkalemie.
Minder dikwels: Hipernatremie.
Senuweestelselversteurings
Dikwels: Hoofpyn, duiseligheid/vertigo.
Hartversteurings
Minder dikwels: Angina pectoris, miokardiale infarksie.
Bloedvatversteurings
Dikwels: Hipotensie.
Respiratoriese, borskas- en mediastinumversteurings
Minder dikwels: Faringitis, rinitis, boonste lugweginfeksie, hoes.
Gastro-intestinale versteurings
Minder dikwels: Naarheid.
Hepatobiliêre versteurings
Minder dikwels: Abnormale lewerfunksie, verhoogde lewerensieme, hepatitis.
Vel- en onderhuidse weefselversteurings
Minder dikwels: Urtikarie, pruritus, uitslag.
Muskuloskeletale en bindweefsel-versteurings
Minder dikwels: Hiperurisemie of jig, rugpyn, mialgie, artralgie.
Nier- en urienwegversteurings
Dikwels: Ingekorte nierfunksie.
Minder dikwels: Nierversaking by vatbare pasiënte (kyk **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).
Ondersoeke
Minder dikwels: Verhoging in kreatinien, ureum en kalium. Afname in hemoglobien- en hematokritwaardes. Verhoogde lewerensiemwaardes.
BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN
Die simptome van 'n oordosis **ABECARD** kan duiseligheid, hipotensie en tagikardie wees. Bradikardie kan voorkom as gevolg van parasimpatiese (vagus-) stimulering. Indien simptomatiese hipotensie sou voorkom, moet ondersteunende behandeling ingestel word. **ABECARD** kan NIE deur hemodialise verwyder word nie.
IDENTIFIKASIE
ABECARD 8: Ronde, bikonvekse, ongeveer 8 mm in deursnee, wit tot naaswit tablette met 'n breeklyn aan die een kant en gebosseleer op dieselfde kant met "C8".
ABECARD 16: Ronde, bikonvekse, ongeveer 8 mm in deursnee, wit tot naaswit tablette met 'n breeklyn aan die een kant en gebosseleer op dieselfde kant met "C16".
ABECARD 32: Ronde, bikonvekse, ongeveer 10,5 mm in deursnee, wit tot naaswit tablette met 'n breeklyn aan die een kant en gebosseleer op dieselfde kant met "C32".
AANBIEDING
Pakke met 28 of 30 tablette, verpak in deursigtige PVC/PVDC/Aluminium stulpstroke in 'n kartonhouer.
BERGINGSAANWYSINGS
Berg in die oorspronklike verpakking (stulpstroke in die karton), by of onder 25 °C.
HOU MEDISYNE BUITE BEREIK VAN KINDERS.
REGISTRASIENOMMERS
ABECARD 8: 46/7.1.3/0231; **ABECARD 16**: 46/7.1.3/0232; **ABECARD 32**: 46/7.1.3/0233
NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKATE
Lasara Traders (Pty) Ltd,
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INLIGTINGSPAMFLET VIR DIE PASIËNT
SKEDULERINGSTATUS S3
HANDELSNAME (EN DOSEERVORM)
ABECARD 8 ™ (tablette)
ABECARD 16 ™ (tablette)
ABECARD 32 ™ (tablette)
Lees die hele pamflet sorgvuldig deur voordat jy ABECARD begin gebruik.
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil deurlees.
- Indien jy nog vrae het, vra asseblief jou dokter of apteker.
- **ABECARD** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

WAT ABECARD BEVAT
- Die aktiewe bestanddeel is kandesartaansileksetil.
  ABECARD 8: Elke tablet bevat 8 mg kandesartaansileksetil
  ABECARD 16: Elke tablet bevat 16 mg kandesartaansileksetil
  ABECARD 32: Elke tablet bevat 32 mg kandesartaansileksetil
- Bevat 'n suiker (laktose).
- Die ander bestanddele is: natrium-kroskarmellose, hidroksiepropielsellulose, magnesiumstearaat, mieliestysel, triëtielsitraat.

WAARVOOR ABECARD GEBRUIK WORD
ABECARD behoort aan 'n klas van medisyne wat bekend staan as angiotensien-II reseptorblokkers (ARBs). Dit keer dat die bloedvate vernou, waardeur die bloeddruk verlaag en die bloedvloei verbeter.
ABECARD word gebruik om
- ligte of matige hoë bloeddruk (hipertensie) te behandel; of vir
- hartversaking. Hartversaking is 'n toestand waar die hart nie goed genoeg pomp nie. Dit kan lei tot 'n verminderde bloedvloei uit die hart.

VOORDAT JY ABECARD NEEM
Moenie ABECARD neem nie
- indien jy hipersensitief (allergies) is vir die aktiewe bestanddeel in **ABECARD**, of vir enige van die ander bestanddele in die tablet (kyk ook **WAT ABECARD BEVAT**);
- indien jy swanger is, beplan om swanger te raak, of jou baba borsvoed (kyk **Swangerskap en borsvoeding**);
- as jy voorheen angio-edeem met angiotensienomskakelingsensiem (AOE-) blokkers of ARB's gehad het, of hierdie simptome onder enige ander omstandighede gehad het. Sommige tekens kon swelling van die gesig, tong of keel, hyg, veluitslag, intense jeuk, duiseligheid of floute gewees het;
- indien jy 'n geskiedenis van idiopatiese angio-edeem het. Dit is 'n velreaksie wat lyk soos galbulte en dit sluit in swelling van die vel;
- as jy 'n hartsiekte het wat die vloei van die bloed uit die hart blokkeer weens verdikking en verstywing van die wande van die ventrikels (laer-hartkamers);
- jy ernstige nierprobleme het;
- as jy 'n vernouing het van die aortaklep se opening tussen die linkerventrikel (linker onderste hartkamer) en die aorta (die hoofslagaar uit die hart);
- as jy 'n vernouing of verstopping van die bloedvate na beide niere of na 'n enkele werkende nier het;
- as jy watertablette (diuretika) soos spironolaktoon, amiloried of triamtereen neem wat veroorsaak dat jou liggaam kalium terughou;
- as jy porfirie het ('n oorerflike siekte in die metabolisme van die rooibloedsel-pigment, wat die vel of senuweestelsel affekteer); of
- as jy met litium behandel word (wat gebruik kan word vir sielkundige afwykings soos manie).

ABECARD tablette moet nie aan kinders gegee word nie.
Wees versigtig met ABECARD
Vertel jou dokter voordat jy ABECARD neem, as jy
- beplan om swanger te word, of as jy jou baba borsvoed (kyk **Moenie ABECARD neem nie** en ook die belangrike inligting onder **Swangerskap en borsvoeding**);
- ontwater raak (volume-uitputting), byvoorbeeld as jy braking of diarree het, of baie sweet, of as jy 'n beperkte sout-dieet volg of diuretika neem;
- niersiekte het;
- lewersiekte het;
- hoër-as-normale vlakke van kalium in die bloed het; of medisyne neem wat kalium kan verhoog;
- hartversaking het, dit is 'n toestand waar die hart nie genoeg bloed kan pomp om te voldoen aan die liggaam se behoeftes nie;
- geopereer gaan word en narkose (medisyne wat die bewussyn onderdruk tydens operasies) gaan kry; of as jy
- allergies is vir laktose (kyk ook **Belangrike inligting oor sommige bestanddele van ABECARD**).

Inname van ABECARD met kos en drank
ABECARD kan met of sonder kos geneem word.
Vermy alkohol. Alkohol saam met **ABECARD** kan jou bloeddruk verder verlaag en kan veroorsaak dat jy duiselig of lighoofdig voel.
Swangerskap en borsvoeding
Indien jy swanger is, of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige voordat jy ABECARD gebruik.
Jy moet nie ABECARD neem nie
- as jy swanger is, beplan om swanger te raak of indien jy vermoed dat jy swanger is, want **ABECARD** kan jou ongebore baba aantas;
- indien jy jou baba borsvoed.

Let wel
Jy moet onmiddellik jou dokter, apteker of professionele gesondheidsorgkundige inlig as jy **ABECARD** neem en jy vermoed dat jy swanger is. As dit bevestig word dat jy swanger is moet jy so gou moontlik ophou om **ABECARD** te neem. Jou dokter sal 'n ander medisyne voorskryf om jou bloeddruk te beheer.
Vroue in die ouderdomsgroep vir swangerskap moet doeltreffende voorbehoeding verseker.
Bestuur en gebruik van masjinerie
ABECARD kan jou duiselig of lighoofdig laat voel.
Moenie motor bestuur, masjinerie of gereedskap hanteer, of enigiets anders wat gevaarlik kan wees doen nie, totdat jy weet hoe jy op **ABECARD** reageer.
Belangrike inligting oor sommige van die bestanddele van ABECARD
ABECARD bevat laktose (melksuiker). As jy 'n seldsame oorerflike onverdraagsaamheid vir suikers het, lig jou dokter in daarvan; jy moet dan nie **ABECARD** neem nie.
Die gebruik van ander medisyne met ABECARD
Lig altyd jou professionele gesondheidsorgkundige in as jy enige ander medisyne neem. (Dit sluit in komplementêre of tradisionele medisyne).
Maak veral seker dat jou dokter weet dat jy die volgende neem
- litium (kyk hierbo by **Moenie ABECARD neem nie**);
- ander medisyne om jou bloeddruk te verlaag, want hulle kan jou bloeddruk verder verlaag;
- kaliumaanvullings, kaliumbevattende soutvervangers en kaliumsparende diuretika (bv. spironolaktoon, triamtereen of amiloried);
- diuretika ("watertablette").

Voordat jy begin om enige nuwe medisyne (voorskrif of nie-voorskrif) te gebruik, of as jy enige nuwe mediese probleem ontwikkel terwyl jy **ABECARD** gebruik, lig jou dokter, professionele gesondheidsorgkundige of apteker daarvan in.
HOE OM ABECARD TE NEEM
Moenie medisyne wat vir jou voorgeskryf is met ander mense deel nie.
Neem **ABECARD** altyd presies soos jou dokter dit vir jou voorgeskryf het. As jy onseker is, vra jou dokter of apteker.
Die gewone dosis is
Hoë bloeddruk
Die gewone dosis is 1 x **ABECARD** 8 mg tablet een keer daagliks.
Die normale instandhoudingsdosis is 1 x **ABECARD** 8 mg of 1 x **ABECARD** 16 mg tablet een keer daagliks, vir die meeste pasiënte.
Jou dokter kan tot 32 mg een keer daagliks in sommige gevalle voorskryf.
Ongeveer 4 weke se gebruik van **ABECARD** kan nodig wees om jou bloeddruk onder beheer te kry. Hou aan om die medisyne te neem soos wat jou dokter voorgeskryf het, selfs al voel jy goed. Hoë bloeddruk het dikwels geen simptome nie.
Hartversaking
Die gewone dosis waarmee begin word is 4 mg (½ tablet **ABECARD** 8 mg) een keer daagliks.
Jou dokter kan jou dosis geleidelik verhoog tot 32 mg een keer per dag om te help om jou hartversaking te beheer.
ABECARD kan met of sonder kos geneem word, met 'n bietjie water. Neem jou **ABECARD** op dieselfde tyd elke dag.
Gebruik by swart pasiënte
Die bloeddrukverlagende uitwerking kan minder wees by swart as by nie-swart (Kaukasiese, Asiatiese en ander) pasiënte. Jou dokter kan bykomende medisyne, soos watertablette, voorskryf.
Gebruik by kinders
ABECARD is nie geskik vir kinders nie.
Duur van behandeling
Jou dokter sal jou inlig hoe lank jou behandeling met **ABECARD** sal aanhou. Moenie die behandeling vroeg staak nie want jou bloeddruk sal nie meer beheer word nie.
Indien jy die indruk kry dat die effek van **ABECARD** te sterk of te swak is, lig jou dokter of apteker in.
Indien jy meer ABECARD neem as wat jy moet
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
Neem hierdie pamflet en enige oorblywende tablette saam met jou, sodat die dokter weet wat jy geneem het.
Sommige van die simptome van oordosering is lae bloeddruk (jy kan duiselig, lighoofdig en siek voel) en veranderinge in die hartklop (verhoogde hartklop of dalk verlaagde hartklop).
Indien jy vergeet het van 'n dosis ABECARD, of dit oorgeslaan het
Dit is belangrik dat jy jou medisyne elke dag neem. As jy egter vergeet het om een of meer dosisse te neem, neem 'n dosis sodra jy daarvan onthou en gaan dan voort met die normale daaglikse dosis, soos voorgeskryf.
Moenie 'n dubbeldosis neem om op te maak vir oorgeslaande individuele dosisse nie.
MOONTLIKE NEWE-EFFEKTE
ABECARD kan newe-effekte hê.
Nie alle newe-effekte wat vir **ABECARD** aangemeld is, is in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy **ABECARD** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgkundige.
Indien enige van die volgende gebeur, staak ABECARD, vertel jou dokter dadelik daarvan, of gaan na die ongevalle-afdeling by jou naaste hospitaal
- galbulte, erge maagpyn, moeilike asemhaling, swelling van jou gesig, lippe, tong, of keel, duiseligheid of floute, buitengewoon vinnige of onreëlmatige hartklop. Dit kan tekens van angio-edeem wees.

As jy hierdie simptome het, het jy moontlik 'n baie ernstige allergiese reaksie op **ABECARD**. Jy kan dringende mediese aandag of hospitalisering benodig.
Lig jou dokter DADELIK in as jy die volgende tekens waarneem, of gaan na die ongevalle-afdeling by jou naaste hospitaal
- hartaanval of angina pectoris ('n swaar, drukkende, branderige of benoude gevoel op die bors. Die pyn of ongemak begin gewoonlik agter die borsbeen);
- tekens van ontsteking van die lewer, soos koors, naarheid of geel vel en oë;
- minder uriene as normaalweg.

Al hierdie newe-effekte is ernstig. Jy kan dringende mediese aandag benodig.
Sê vir jou dokter as jy enige van die volgende waarneem
Die volgende newe-effekte kan dikwels voorkom
- tekens van herhalende respiratoriese infeksies soos sinus-aandoenings;
- hoë kaliumkonsentrasie in die bloed (hiperkalemie). Kontak jou dokter as jy siek of moeg voel, swak spiere het en tintelende sensasies ervaar. Hy/sy kan bloedtoetse aanvra om te weet of jy te veel kalium in jou bloed het;
- hoofpyn, duiseligheid of 'n ronddraaiende gevoel;
- te lae bloeddruk (sommige tekens kan lighoofdigheid, duiseligheid en floute wees).

Die volgende newe-effekte kom minder dikwels voor
- verminderde aantal witbloedselle (jy kan agterkom dat jy gereeld infeksies kry);
- maklike of oormatige bloeding weens 'n lae bloedplaatjietelling;
- rugpyn, spierpyn, pynlike gewrigte of jig (sommige tekens kan 'n gevoel van warmte, pyn, swelling en uiterste teerheid in 'n gewrig, gewoonlik in 'n groottoongewrig, wees);
- te lae natriumsout-konsentrasie in jou bloed ('n paar tekens kan wees dat jy siek voel, met 'n hoofpyn en spierspasmas en krampe. Jou dokter kan dalk bloedtoetse aanvra om te sien of jy hierdie tekort het);
- hoes, koors of seerkeel, toe neus;
- siek gevoel (naarheid);
- veluitslag.

Indien jy enige newe-effekte waarneem wat nie in hierdie pamflet vermeld word nie, lig asseblief jou dokter of apteker in.
BEWARING EN WEGDOENING VAN ABECARD
Hou buite bereik van kinders.
Berg in die oorspronklike verpakking (hou die stulpstroke in die karton), by of onder 25 °C.
Moenie jou medisyne in die badkamer aanhou nie.
Moenie **ABECARD** na die vervaldatum wat op die karton en stulpstroke gedruk is, gebruik nie.
Neem vervalde of ongebruikte medisyne terug na jou apteker om veilig daarvan ontslae te raak. Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.
AANBIEDING VAN ABECARD
Pakke met 28 of 30 tablette, verpak in deursigtige PVC/PVDC/Aluminium stulpstroke in 'n kartondoos.
IDENTIFIKASIE VAN ABECARD
ABECARD 8: Ronde, bikonvekse, ongeveer 8 mm in deursnee, wit tot naaswit tablette met 'n breeklyn aan die een kant en gebosseleer op dieselfde kant met "C8".
ABECARD 16: Ronde, bikonvekse, ongeveer 8 mm in deursnee, wit tot naaswit tablette met 'n breeklyn aan die een kant en gebosseleer op dieselfde kant met "C16".
ABECARD 32: Ronde, bikonvekse, ongeveer 10,5 mm in deursnee, wit tot naaswit tablette met 'n breeklyn aan die een kant en gebosseleer op dieselfde kant met "C32".
REGISTRASIENOMMERS
ABECARD 8: 46/7.1.3/0231; **ABECARD 16**: 46/7.1.3/0232; **ABECARD 32**: 46/7.1.3/0233
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