PROFESSIONAL INFORMATION FOR VALHEFT 40, 80 and 160

SCHEDULING STATUS
S3

PROPRIETARY NAME AND DOSAGE FORM
VALHEFT 40 film coated tablet
VALHEFT 80 film coated tablet
VALHEFT 160 film coated tablet

COMPOSITION
VALHEFT 40: Each film coated tablet contains 40 mg valsartan.
VALHEFT 80: Each film coated tablet contains 80 mg valsartan.
VALHEFT 160: Each film coated tablet contains 160 mg valsartan.

Inactive ingredients:
Anhydrous lactose, crospovidone, magnesium stearate, microcrystalline cellulose and silica.
VALHEFT 40 and **160** also contain Opadry Yellow (consisting of hypromellose, macrogol, titanium dioxide and yellow iron oxide).
VALHEFT 80 also contains Opadry Pink (consisting of hypromellose, macrogol, titanium dioxide, red iron oxide and yellow iron oxide).
Contains sugar:
Each **VALHEFT 40** tablet contains 51,3 mg lactose.
Each **VALHEFT 80** tablet contains 102,5 mg lactose.
Each **VALHEFT 160** tablet contains 205 mg lactose.

PHARMACOLOGICAL CLASSIFICATION
A 7.1.3 Vascular medicine - other hypotensives

PHARMACOLOGICAL ACTION
Pharmacodynamic properties:
Valsartan is a non-peptide angiotensin II receptor antagonist that selectively blocks the binding of angiotensin II to the AT_1 receptor in tissues such as vascular smooth muscle and the adrenal gland. In the renin-angiotensin system, angiotensin I is converted by angiotensin-converting enzyme (ACE) to form angiotensin II. 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. Valsartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by inhibiting the binding of angiotensin II to the AT_1 receptor.

Pharmacokinetic properties:
Valsartan is well absorbed after oral administration, with a bioavailability of approximately 23 %. Peak plasma concentrations occur 2 to 4 hours after an oral dose. Valsartan shows multi-exponential decay kinetics ($t_{½}$ α < 1 h and $t_{½}$ β about 9 h).
The pharmacokinetics of valsartan is linear in the dose range tested. There is no change in the kinetics of valsartan on repeated administration and little accumulation when dosed once daily. Plasma concentrations are similar in males and females.
Valsartan is highly bound to serum protein (94 to 97 %), mainly serum albumin. Steady-state volume of distribution is low (about 17 ℓ). Plasma clearance is relatively slow (about 2 ℓ/h) when compared with hepatic blood flow (about 30 ℓ/h).

Valsartan is not significantly metabolised and is excreted mainly unchanged via the bile. Following an oral dose about 70 % is excreted in the faeces and 30 % in urine.
The mean elimination half-life is about 9 hours.
When valsartan is given with food, the area under the plasma concentration curve (AUC) of valsartan is reduced by 48 %, although from about 8 hours post dosing plasma valsartan concentrations are similar for the fed and fasted group. This reduction in AUC, however, is not accompanied by a clinically significant reduction in the therapeutic effect, and valsartan can therefore be given either with or without food.

The average time to peak concentration and elimination half-life of valsartan in heart failure patients are similar to that observed in healthy volunteers. AUC and C_{max} values of valsartan increase linearly and are almost proportional with increasing dose over the clinical dosing range (40 mg to 160 mg twice a day). The average accumulation factor is about 1,7. The apparent clearance of valsartan following oral administration is approximately 4,5 ℓ/h. Age does not affect the apparent clearance in heart failure patients.

Elderly patients:
A significantly higher systemic exposure to valsartan was observed in elderly subjects than in young subjects; however, this has not been shown to have any clinical significance.

Renal impairment:
Renal clearance accounts for only 30 % of total plasma clearance and no correlation is seen between renal function and systemic exposure to valsartan. Dose adjustment is therefore not required in patients with mild renal impairment. No studies have been performed in patients undergoing dialysis. However, valsartan is highly bound to plasma protein and is unlikely to be removed by dialysis.

Hepatic impairment:
About 70 % of the absorbed dose is excreted in the bile mainly as unchanged compound. Valsartan does not undergo extensive biotransformation and systemic exposure to valsartan is not correlated with the degree of liver dysfunction. No dose adjustment for valsartan is therefore necessary in patients with hepatic insufficiency of non-biliary origin and without cholestasis. The AUC with valsartan has been observed to be approximately double in patients with biliary cirrhosis or biliary obstruction (see **WARNINGS AND SPECIAL PRECAUTIONS**).

INDICATIONS
Hypertension: Treatment of mild to moderate hypertension.
Heart failure: Treatment of heart failure (NYHA class II - IV).

CONTRAINDICATIONS
- Hypersensitivity to valsartan or any of the excipients of **VALHEFT** (see **COMPOSITION**).
- Pregnancy and lactation (see **PREGNANCY AND LACTATION**).
- Severe renal function impairment (creatinine clearance less than 30 ml/min).
- A history of angioedema related to previous therapy with angiotensin converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs): These patients must never again be given these medicines.
- Hereditary or idiopathic angioedema.
- Hypertrophic obstructive cardiomyopathy (HOCM).
- 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, and amiloride (see **INTERACTIONS**).
- Porphyria.
- Lithium therapy: Concomitant administration with **VALHEFT** may lead to toxic blood concentrations of lithium (see **INTERACTIONS**).
- The concomitant use of **VALHEFT** with aliskiren-containing products is contraindicated (see **WARNINGS AND SPECIAL PRECAUTIONS** and **INTERACTIONS**).

WARNINGS AND SPECIAL PRECAUTIONS

Should a woman become pregnant while receiving **VALHEFT**, the treatment should be stopped promptly and switched to a different class of antihypertensive medicine. Should a woman contemplate pregnancy, the doctor should consider alternative medication. (See **CONTRAINDICATIONS** and **PREGNANCY AND LACTATION**.)

Hypotension and electrolyte/fluid imbalance:
Sodium- and/or volume-depletion, due to excessive perspiration, vomiting, diarrhoea, prolonged diuretic therapy, dialysis or dietary salt restriction may increase the risk of symptomatic hypotension. In sodium-depleted and/or volume-depleted patients, such as those receiving high doses of diuretics, and/or patients with moderate to severe renal impairment, symptomatic hypotension may occur after initiation of therapy with **VALHEFT**. Sodium- and/or volume-depletion should be corrected before starting treatment with **VALHEFT** (for example, by reducing the diuretic dose).
If hypotension occurs, the patient should be placed in the supine position and, if necessary, given an intravenous infusion of normal saline. Treatment can be continued once blood pressure has stabilised.

Renal artery stenosis:
Short-term administration of **VALHEFT** to patients with renovascular hypertension secondary to unilateral renal artery stenosis, did not induce any significant changes in renal haemodynamics or serum creatinine. However, since other medicines that affect the renin-angiotensin-aldosterone system may increase blood urea and serum creatinine in patients with bilateral or unilateral renal artery stenosis, monitoring of both parameters is recommended as a safety measure (see **CONTRAINDICATIONS**).

Renal impairment:
No dosage adjustment is required for patients with mild to moderate renal impairment. However, in severe cases (creatinine clearance < 30 ml/min) insufficient data are available. **VALHEFT** should not be used because of increased side effects (see **CONTRAINDICATIONS**).

Hepatic impairment:
No dosage adjustment is required for patients with hepatic insufficiency of non-biliary origin and without cholestasis. **VALHEFT** is mostly eliminated unchanged in the bile, and patients with biliary obstructive disorders showed lower valsartan clearance (see **Pharmacokinetic properties**). Caution should be exercised when using **VALHEFT** in patients with biliary obstructive disorders. **VALHEFT** is not recommended for use in patients with severe hepatic impairment.

Hyperkalaemia:
Since hyperkalaemia may occur, serum potassium concentrations should be monitored, especially in the elderly and patients with renal impairment and the concomitant use of potassium-sparing diuretics should generally be avoided (see **CONTRAINDICATIONS** and **INTERACTIONS**).

Heart failure:
Use of **VALHEFT** in patients with heart failure commonly results in some reduction in blood pressure, but discontinuation of **VALHEFT** therapy because of continuing symptomatic hypotension is not usually necessary provided dosing instructions are followed. Caution should be observed when initiating therapy in patients with heart failure (see **DOSAGE AND DIRECTIONS FOR USE**).
In patients with heart failure, caution should be observed with concurrent administration of ACE inhibitors, beta-blockers and **VALHEFT** as an increase in mortality has been reported on this triple therapy (see **INTERACTIONS**).

Dual blockade of the renin-angiotensin-aldosterone system (RAAS):
There is evidence that the concomitant use of ACE inhibitors, angiotensin II receptor blockers (ARBs) or aliskiren may increase the risk of hypotension, hyperkalaemia and decreases renal function (including acute renal failure). Dual blockade of RAAS through the combined use of **VALHEFT** and aliskiren is therefore contraindicated (see **CONTRAINDICATIONS** and **INTERACTIONS**).
VALHEFT should not be used concomitantly with aliskiren (see **CONTRAINDICATIONS**).
In patients with severe heart failure whose renal function may depend on the activity of the RAAS, treatment with ACE inhibitors or angiotensin receptor antagonists has been associated with oliguria and/or progressive uraemia and with acute renal failure and/or death. Evaluation of patients with heart failure should always include assessment of renal function.

Effects on ability to drive and use machines:
It is advisable to exercise caution when driving, operating machinery or performing tasks requiring alertness, until the effects of **VALHEFT** are known.

Contains sugar (anhydrous lactose):
Patients with the rare hereditary conditions of lactose or galactose intolerance, e.g. galactosaemia, Lapp lactase deficiency, or glucose-galactose malabsorption should not take **VALHEFT**.

INTERACTIONS
- Clinical trial data has shown that dual blockade of the renin-angiotensin-aldosterone-system (RAAS) through the combined use of ACE inhibitors, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of adverse events such as hypotension, hyperkalaemia and decreased renal function (see **CONTRAINDICATIONS, WARNINGS AND SPECIAL PRECAUTIONS**).
- Concomitant use of potassium-sparing diuretics, potassium supplements or salt substitutes containing potassium may lead to increased serum potassium and in heart failure patients to increased serum creatinine levels (see **CONTRAINDICATIONS**).
- As **VALHEFT** is not metabolised to a significant extent, clinically relevant interactions in the form of metabolic induction or inhibition of the cytochrome P450 isoenzyme system is not expected.
- The antihypertensive effects of **VALHEFT** may be potentiated by medicines that lower blood pressure.
- Increased mortality has been reported with valsartan in patients with heart failure also receiving both ACE inhibitors and beta blockers and it should be avoided in such patients (see **WARNINGS AND SPECIAL PRECAUTIONS**).
- Concurrent use of **VALHEFT** with lithium may reduce lithium clearance and result in lithium toxicity. Lithium levels should be regularly monitored (see **CONTRAINDICATIONS**).
- Nonsteroidal anti-inflammatory medicine (NSAIDs), including cyclo-oxygenase-2 inhibitors, may reduce the effect of diuretics and the antihypertensive effect of **VALHEFT**. Patients taking NSAIDs concomitantly with **VALHEFT** should be adequately hydrated and renal function should be monitored.
- No interactions of clinical significance have been found during clinical trials with the following compounds: cimetidine, warfarin, furosemide, digoxin, atenolol, indomethacin, hydrochlorothiazide, amlodipine and glibenclamide.

PREGNANCY AND LACTATION
Pregnancy:
Safety has not been established. **VALHEFT** is not to be used in pregnancy (see **CONTRAINDICATIONS**). Medicines affecting the renin-angiotensin system, such as **VALHEFT**, can cause embryonal toxicity, foetal and neonatal morbidity and mortality when administered to pregnant women. When pregnancy is planned or confirmed, **VALHEFT** should be discontinued as soon as possible.
Women of childbearing age should ensure adequate contraception.

Lactation:
Safety has not been established. **VALHEFT** should not be used during breastfeeding (see **CONTRAINDICATIONS**).

DOSAGE AND DIRECTIONS FOR USE
VALHEFT can be taken with or without food.

Hypertension:
The recommended dose of **VALHEFT** is 80 mg or 160 mg once daily, irrespective of race, age or gender.
The antihypertensive effect is substantially present within 2 weeks and maximal effects are seen after 4 weeks. In patients whose blood pressure is not adequately controlled, the daily dose may be increased to 320 mg, or a diuretic may be added.

VALHEFT may also be administered with other antihypertensive medicines.

Heart failure:
The recommended starting dose of **VALHEFT** is 40 mg twice daily. Up-titration to 80 mg and 160 mg twice daily should be done to the highest dose tolerated by the patient. Consideration should be given to reducing the dose of concomitant diuretics. The maximum daily dose administered is 320 mg in divided doses.
Evaluation of patients with heart failure should always include assessment of renal function.

NOTE for all indications:
No initial dosage adjustment is required for patients with mild renal impairment (where the creatinine clearance is above 70 ml/min) or for patients with hepatic insufficiency of non-biliary origin and without cholestasis.

VALHEFT is contraindicated in patients with severe renal impairment.

Use in children and adolescents:
The safety and efficacy of **VALHEFT** have not been established in children and adolescents (below the age of 18 years).

SIDE EFFECTS
Infections and infestations:
Frequent: viral infections
Less frequent: upper respiratory tract infection, pharyngitis, sinusitis, rhinitis

Blood and the lymphatic system disorders:
Frequent: neutropenia
Less frequent: thrombocytopenia

Immune system disorders:
Less frequent: hypersensitivity including serum sickness

Metabolism and nutrition disorders:
Less frequent: hyperkalaemia

Psychiatric disorders:
Less frequent: insomnia, decreased libido

Nervous system disorders:
Frequent: postural dizziness
Less frequent: syncope, dizziness, headache

Eye disorders:
Less frequent: blurred vision

Ear and labyrinth disorders:
Less frequent: vertigo

Cardiac disorders:
Less frequent: cardiac failure

Vascular disorders:
Frequent: postural (orthostatic) hypotension
Less frequent: hypotension (may occur in patients with volume depletion), vasculitis

Respiratory, thoracic and mediastinal disorders:
Less frequent: cough

Gastrointestinal disorders:
Less frequent: diarrhoea, abdominal pain, nausea

Hepatobiliary disorders:
Frequency unknown: hepatitis

Skin and subcutaneous tissue disorders:
Less frequent: angioedema, rash, pruritus, urticaria

Musculoskeletal, connective tissue and bone disorders:
Less frequent: back pain, arthralgia, myalgia, rhabdomyolysis

Renal and urinary disorders:
Less frequent: renal impairment, acute renal failure, renal insufficiency

General disorders and administration site conditions:
Less frequent: fatigue, asthenia, oedema
Frequency unknown: alopecia

Investigations:
Less frequent: Elevated liver enzymes. Decreased: haemoglobin, haematocrit, white blood cells; increased: serum creatinine, potassium, total bilirubin.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
Symptoms:
Overdose with **VALHEFT** may result in marked hypotension, which could lead to depressed level of consciousness, circulatory collapse and/or shock. Bradycardia or tachycardia may also occur with **VALHEFT** overdose.

Treatment:
If the ingestion is recent, vomiting should be induced. Otherwise, the usual treatment would be intravenous infusion of normal saline solution. It is unlikely to be removed by haemodialysis.

IDENTIFICATION
VALHEFT 40: Yellow coloured, round, biconvex, film coated tablets debossed with 'J' on one side and '40' on the other.
VALHEFT 80: Peach coloured, round, biconvex, film coated tablets, scored on one side and debossed with '80' on scored side and 'J' on the other.
VALHEFT 160: Yellow coloured, oval shaped, biconvex, film coated tablets, scored on one side and debossed with '160' on scored side and 'J' on the other.

PRESENTATION
3 x blister strips each containing 10 tablets are placed into a carton box (30 tablets per pack). The blister strips are comprised of aluminium foil and a multilayer base film (OPA/aluminium foil/PVC).

STORAGE INSTRUCTIONS
Store at or below 25 °C.
Keep blister strips in outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS
VALHEFT 40: 46/7.1.3/0743
VALHEFT 80: 46/7.1.3/0744
VALHEFT 160: 46/7.1.3/0745

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
LeBasi Pharmaceuticals CC
Jankra Building, 2nd Floor
3 O.R. Tambo Street
Potchefstroom 2531

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION
27 July 2017

LI0121/18A

Patient information leaflet for VALHEFT 40, 80 and 160

SCHEDULING STATUS
Schedule 3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
VALHEFT 40 film coated tablet
VALHEFT 80 film coated tablet
VALHEFT 160 film coated tablet

Read all of this leaflet carefully before you start taking VALHEFT.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **VALHEFT** 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.

1. WHAT VALHEFT CONTAINS
Active ingredient: Each film coated tablet contains 40 mg, 80 mg or 160 mg valsartan respectively.

The other ingredients are anhydrous lactose, crospovidone, magnesium stearate, microcrystalline cellulose, and silica.
VALHEFT 40 and **160** also contain Opadry Yellow (consisting of hypromellose, macrogol, titanium dioxide and yellow iron oxide), and **VALHEFT 80** also contains Opadry Pink (consisting of hypromellose, macrogol, titanium dioxide, red iron oxide and yellow iron oxide).
Contains sugar:
Each **VALHEFT 40** tablet contains 51,3 mg lactose.
Each **VALHEFT 80** tablet contains 102,5 mg lactose.
Each **VALHEFT 160** tablet contains 205 mg lactose.

2. WHAT VALHEFT IS USED FOR
Valsartan helps blood vessels relax and so reduces strain on the heart.
- **VALHEFT** is used to treat high blood pressure (hypertension).
- **VALHEFT** is used to treat symptomatic heart failure.

3. BEFORE YOU TAKE VALHEFT
Do not take VALHEFT:
- If you are hypersensitive (allergic) to valsartan or any of the other ingredients of **VALHEFT** (see **WHAT VALHEFT CONTAINS**).
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).
- You have a kidney disorder.
- If you have had angioedema (swelling of your face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking an angiotensin-converting enzyme inhibitor (ACE inhibitor) or an angiotensin receptor blocker, such as **VALHEFT**.
- If you have hypertrophic obstructive cardiomyopathy, a serious heart disorder where the muscles of the heart are thickened, interfering with normal blood flow.
- If you have narrowing of the blood vessels to both kidneys or to a single functioning kidney.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of your heart) and the aorta (the main artery leading away from your heart).
- If you are taking diuretics (water tablets) such as spironolactone, triamterene or amiloride, that cause your body to retain potassium.
- If you have a condition called porphyria (a metabolic disorder).
- If you are taking lithium (used to treat some mood disorders).
- If you are using products containing aliskiren (used to treat high blood pressure).

Take special care with VALHEFT:
- Low blood pressure (symptomatic hypotension) is likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy (water tablets), low-salt diet, diarrhoea, or vomiting. The water and electrolyte balance in your body should be corrected before you start treatment with **VALHEFT**.
- If you have a severe kidney disease.
- If you have a liver disorder where the bile flow is obstructed.
- If you have elevated potassium levels in your blood. Potassium-sparing diuretics should be avoided.
- If you are an elderly patient.

Taking VALHEFT with food and drink:
VALHEFT can be taken with or without food.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **VALHEFT**.
DO NOT take **VALHEFT** tablets if you are pregnant, suspect that you are pregnant, or are planning to become pregnant.
DO NOT take **VALHEFT** tablets if you are breastfeeding your baby.
If you are a woman of childbearing age, you must use effective contraception.

Driving and using machinery:
VALHEFT may cause dizziness and impair your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention, until you know how **VALHEFT** will affect you.

Important information about some of the ingredients of VALHEFT:
VALHEFT contains a sugar called anhydrous lactose. Patients with the rare hereditary conditions of galactose intolerance, e.g. galactosaemia or glucose-galactose malabsorption, should not take **VALHEFT**.

Taking other medicines with VALHEFT:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor or pharmacist if you are currently using:
- Other medicines that lower blood pressure, especially water tablets (diuretics) or aliskiren.
- Medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium or potassium-sparing medicines.
- Lithium, a medicine used to treat some types of mood disorders.
- Nonsteroidal anti-inflammatory medicines (NSAIDs), e.g. aspirin or indomethacin.
- If you are being treated for heart failure, a triple combination with ACE inhibitors and beta blockers is not recommended.

If you are due to have an operation, tell the anaesthetist or the medical staff you are taking **VALHEFT** tablets.

4. HOW TO TAKE VALHEFT
Do not share medicines prescribed for you with any other person.
Always take **VALHEFT** exactly as your doctor has instructed you.
The usual dose is 40 mg, 80 mg or 160 mg once daily.
Your doctor may prescribe different doses, depending on your condition. You should check with your doctor or pharmacist if you are unsure.
The tablets should be taken at about the same time each day.
Do not stop treatment early because your disease may get worse.
If you have the impression that the effect of **VALHEFT** is too strong or too weak, tell your doctor or pharmacist.

If you take more VALHEFT 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 this leaflet and the rest of the remaining **VALHEFT** tablets with you so the doctor will know what you have taken. You may experience severe dizziness and/or fainting as well as a slow or fast heartbeat.

If you forget to take VALHEFT:
If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **VALHEFT** at the next regularly scheduled time.
Do not take a double dose to make up for the forgotten individual doses.

5. POSSIBLE SIDE EFFECTS
VALHEFT can have side effects.
Not all side effects reported for **VALHEFT** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **VALHEFT**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **VALHEFT** 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 **VALHEFT**. 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:
Side effects that may occur frequently:
- You frequently get infections due to a lack of white blood cells.
- Viral infections.

Side effects that may occur less frequently:
- Your blood vessels get inflamed, heart problems.
- Swelling of your body (oedema).
- You get an infection in your airways.
- Diarrhoea, stomach pain, nausea (feeling sick).
- Blurred vision.
- Muscle tenderness or weakness (myalgia), painful, swollen joints (arthralgia).
- You bleed or bruise more easily than normal due to a decreased number of platelets in your blood.
- You feel tired and look pale, because of a decreased number of red blood cells.
- Elevated levels of potassium in your blood.
- There is a problem with the way your liver or kidneys work.

Side effects occurring with unknown frequency:
- Liver disease with nausea, vomiting, fever, yellowing of the skin and whites of the eyes (hepatitis).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

Side effects that may occur frequently:
- Dizziness, light-headedness (especially when getting up from a lying or sitting position).
- Skin rash.

Side effects that may occur less frequently:
- Low blood pressure, problems sleeping.
- Cough, stuffy nose, inflammation of the sinuses, sore throat.
- Fatigue, unusual tiredness, decreased libido.
- Headache, a spinning feeling in your head.
- Elevated levels of potassium in your blood, elevated liver enzymes.

Side effects occurring with unknown frequency:
- Hair loss.

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

6. STORING AND DISPOSING OF VALHEFT
- Store at or below 25 °C.
- Keep blister strips in outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

7. PRESENTATION OF VALHEFT
3 x blister strips each containing 10 tablets are placed into a carton box (30 tablets per pack). The blister strips are comprised of aluminium foil and a multilayer base film (OPA/aluminium foil/PVC).

8. IDENTIFICATION OF VALHEFT
VALHEFT 40: Yellow coloured, round, biconvex, film coated tablets debossed with 'J' on one side and '40' on the other.
VALHEFT 80: Peach coloured, round, biconvex, film coated tablets, scored on one side and debossed with '80' on scored side and 'J' on the other.
VALHEFT 160: Yellow coloured, oval shaped, biconvex, film coated tablets, scored on one side and debossed with '160' on scored side and 'J' on the other.

9. REGISTRATION NUMBERS
VALHEFT 40: 46/7.1.3/0743
VALHEFT 80: 46/7.1.3/0744
VALHEFT 160: 46/7.1.3/0745

10. NAME AND ADDRESS OF REGISTRATION HOLDER
LeBasi Pharmaceuticals CC
Jankra Building, 2nd Floor
3 O.R. Tambo Street
Potchefstroom 2531
Tel. no.: 018 297 4059

11. DATE OF PUBLICATION
27 July 2017

LI0121/18A

PROFESSIONELE INLIGTING VIR VALHEFT 40, 80 en 160

SKEDULERINGSTATUS
S3

HANDELSNAAM EN DOSEERVORM
VALHEFT 40 filmbedekte tablet
VALHEFT 80 filmbedekte tablet
VALHEFT 160 filmbedekte tablet

SAMESTELLING
VALHEFT 40: Elke filmbedekte tablet bevat 40 mg valsartaan.
VALHEFT 80: Elke filmbedekte tablet bevat 80 mg valsartaan.
VALHEFT 160: Elke filmbedekte tablet bevat 160 mg valsartaan.

Onaktiewe bestanddele:
Anhidriese laktose, krospovidoon, magnesiumstearaat, mikrokristallyne sellulose en silika.
VALHEFT 40 en **160** bevat ook Opadry Yellow (bestaande uit hipromellose, makrogol, titaandioksied en geel ysteroksied).
VALHEFT 80 bevat ook Opadry Pink (bestaande uit hipromellose, makrogol, titaandioksied, rooi ysteroksied en geel ysteroksied).
Bevat suiker:
Elke **VALHEFT 40** tablet bevat 51,3 mg laktose.
Elke **VALHEFT 80** tablet bevat 102,5 mg laktose
Elke **VALHEFT 160** tablet bevat 205 mg laktose.

FARMAKOLOGIESE KLASSIFIKASIE:
A 7.1.3 Vaskulêre medisyne – ander hipotensiewe middels

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe:
Valsartaan is 'n nie-peptied angiotensien II reseptor antagonis, wat die binding van angiotensien II aan die AT_1-reseptor selektief blokkeer in weefsel soos vaskulêre gladdespier en die bynier. By die renien-angiotensienstelsel word angiotensien I na angiotensien II omgeskakel deur angiotensien-omskakelingsensiem (ACE). Angiotensien II stimuleer die adrenale korteks om aldosteroon te sintetiseer en af te skei, wat die ekskresie van natrium verlaag en die ekskresie van kalium verhoog. Angiotensien II werk as 'n vasokonstriktor in vaskulêre gladdespier. Valsartaan blokkeer die bloedvatvernouende en aldosteroonsekreterende effekte van angiotensien II deur die binding van die angiotensien II aan die AT_1-reseptor te inhibeer.

Farmakokinetiese eienskappe:
Valsartaan word goed geabsorbeer na orale toediening, met 'n biobeskikbaarheid van ongeveer 23 %. Piek plasmakonsentrasies kom 2 tot 4 uur na 'n orale dosis voor. Kinetika van valsartaan vertoon multi-eksponensiële verval ($t_{½}$ $\alpha < 1$ h en $t_{½}$ β ongeveer 9 h).
Die farmakokinetika van valsartaan is lineêr in die reikwydte van die dosis wat getoets is. Daar is geen verandering in die kinetika van valsartaan met herhaalde toediening nie en weinig akkumulasie wanneer dit een keer per dag geneem word. Plasmakonsentrasies is soortgelyk by mans en vrouens.
Valsartaan is hoogs gebonde aan serumproteïen (94 tot 97 %), hoofsaaklik serumalbumien. Volume van verspreiding by ewewigstoestande is laag (ongeveer 17 ℓ). Plasma-opruiming is relatief stadig (ongeveer 2 ℓ/h) wanneer dit vergelyk word met hepatiese bloedvloei (ongeveer 30 ℓ/h).
Valsartaan word nie beduidend gemetaboliseer nie en word hoofsaaklik onveranderd in die gal uitgeskei. Ná 'n orale dosis word ongeveer 70 % in die feses uitgeskei en 30 % in die urine.
Die gemiddelde halfleeftyd is ongeveer 9 uur.
Wanneer valsartaan met kos gegee word, is die area onder die plasmakonsentrasie-kurwe (AOK) van valsartaan 48 % kleiner, alhoewel die valsartaankonsentrasies soortgelyk is vir die gevoede en vastende groepe vanaf ongeveer 8 uur ná dosering. Hierdie verlaging in AOK het egter nie 'n gepaardgaande klinies beduidende vermindering in terapeutiese uitwerking nie, en valsartaan kan dus met of sonder voedsel gegee word.

Die gemiddelde tyd tot piek konsentrasie en eliminasiehalfleeftyd van valsartaan by pasiënte met hartversaking is soortgelyk aan dit wat by gesonde vrywilligers waargeneem is. Die AOK en C_{maks}-waardes van valsartaan neem lineêr toe en is feitlik proporsioneel aan die toenemende dosis oor die kliniese doseringsreikwydte (40 mg tot 160 mg twee keer 'n dag). Die gemiddelde akkumulasiefaktor is ongeveer 1,7. Die oënskynlike opruiming van valsartaan ná orale toediening is ongeveer 4,5 ℓ/h. Ouderdom beïnvloed nie die oënskynlike opruiming by pasiënte met hartversaking nie.

Bejaarde pasiënte:
Daar is 'n beduidend hoër sistemiese blootstelling aan valsartaan waargeneem by bejaarde persone as by jonger persone; daar is egter nie getoon dat dit van enige kliniese belang is nie.

Renale belemmering:
Renale opruiming verteenwoordig net 30 % van totale plasma-opruiming en geen korrelasie word gesien tussen nierfunksie en sistemiese blootstelling aan valsartaan nie. Dit is dus nie nodig om die dosis aan te pas by pasiënte met ligte renale belemmering nie. Daar is geen studies uitgevoer by pasiënte wat dialise ondergaan nie. Valsartaan is egter hoogs gebonde aan plasmaproteïen en dit is onwaarskynlik dat dit deur dialise verwyder sal word.

Hepatiese belemmering:
Ongeveer 70 % van die geabsorbeerde dosis word in die gal uitgeskei, hoofsaaklik as die onveranderde verbinding. Valsartaan ondergaan nie ekstensiewe biotransformasie nie en sistemiese blootstelling aan valsartaan korreleer nie met die mate van lewerdisfunksie nie. Dit is dus nie nodig om die dosis van valsartaan aan te pas by pasiënte met hepatiese belemmering van nie-bilière oorsprong en sonder cholestase nie. Dit is waargeneem dat die AOK van valsartaan ongeveer dubbel is by pasiënte met bilière sirrose of bilière obstruksie (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).

INDIKASIES
Hipertensie: Behandeling van geringe tot matige hipertensie.
Hartversaking: Behandeling van hartversaking (NYHA klas II – IV).

KONTRA-INDIKASIES
- Hipersensitiwiteit vir valsartaan of enige van die onaktiewe bestanddele van **VALHEFT** (sien **SAMESTELLING**).
- Swangerskap en borsvoeding (sien **SWANGERSKAP EN BORSVOEDING**).
- Erge nierfunksiebelemmering (kreatinienopruiming minder as 30 ml/min).
- 'n Geskiedenis van angio-edeem verwant aan vorige terapie met angiotensienomskakelingsensiem (AOE) inhibeerders of angiotensienreseptorblokkers (ARB's): Hierdie pasiënte moet nooit weer hierdie medisynes ontvang nie.
- Oorerflike of idiopatiese angio-edeem.
- Hipertrofiese obstruktiewe kardiomiopatie (HOCM).
- Bilaterale renale arteriestenose.
- Renale arteriestenose by pasiënte met net een nier.
- Stenose van die aorta.
- Gelyktydige terapie met kaliumsparende diuretika, soos spiroonlaktoon, triamtereen, en amiloried (sien **INTERAKSIES**).
- Porfirie.
- Litiumterapie: Gepaardgaande toediening met **VALHEFT** mag tot toksiese bloedkonsentrasies van litium lei (sien **INTERAKSIES**).
- Die gepaardgaande gebruik van **VALHEFT** met aliskiren-bevattende produkte is teenaangedui (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS** en **INTERAKSIES**).

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS

Indien 'n vrou swanger sou raak terwyl sy **VALHEFT** neem, moet die behandeling onmiddellik gestaak word en moet na 'n verskillende klas antihipertensiewe medisyne oorgeskakel word. Indien 'n vrou oorweeg om swanger te raak, moet die dokter alternatiewe medikasie oorweeg. (Sien **KONTRA-INDIKASIES** en **SWANGERSKAP EN BORSVOEDING**).

Hipotensie en elektroliet/vloeistofwanbalans:
Natrium- en/of volume-uitputting, weens oormatige perspirasie, braking, diarree, verlengde diuretiese terapie, dialise of soutbeperkte dieet mag die risiko vir simptomatiese hipotensie verhoog. By pasiënte met natrium- en/of volume-uitputting, soos by pasiënte wat hoë dosisse diuretika ontvang, en/of pasiënte met matige tot erge renale belemmering, mag simptomatiese hipotensie voorkom nadat begin is met **VALHEFT** terapie. Natrium- en/of volume-uitputting moet reggestel word voordat behandeling met **VALHEFT** begin word (deur byvoorbeeld die dosis van die diuretikum te verminder).
Indien hipotensie voorkom, laat die pasiënt plat lê en, indien nodig, dien fisiologiese soutoplossing deur 'n binneaarse infusie toe. Behandeling kan voortgesit word sodra die bloeddruk gestabiliseer het.

Renale arteriestenose:
Korttermyn-toediening van **VALHEFT** aan pasiënte met renovaskulêre hipertensie sekondêr aan eensydige renale arteriestenose, het nie enige beduidende veranderings in die renale hemodinamika of serumkreatinien geïnduseer nie. Aangesien ander medisynes wat die renien-angiotensien-aldosteroonstelsel beïnvloed egter bloedureum en serumkreatinien kan verhoog by pasiënte met bilaterale arteriestenose of stenose van die slagaar na 'n enkele funksionele nier, word aanbeveel dat albei parameters as 'n veiligheidsmaatreël gemonitor word (sien **KONTRA-INDIKASIES**).

Renale belemmering:
Geen dosisaanpassing is nodig vir pasiënte met geringe tot matige renale belemmering nie. Daar is egter onvoldoende data beskikbaar in ernstige gevalle (kreatinienopruiming < 30 ml/min). **VALHEFT** moenie gebruik word nie, weens 'n toename in newe-effekte (sien **KONTRA-INDIKASIES**).

Hepatiese belemmering:
Geen dosisaanpassing is nodig vir pasiënte met hepatiese belemmering wat nie van bilière oorsprong is nie en wat sonder cholestase is. **VALHEFT** word grootliks onveranderd in die gal uitgeskei, en pasiënte met bilière obstruktiewe versteurings het laer opruiming van valsartaan getoon (sien **Farmakokinetiese eienskappe**). **VALHEFT** moet met omsigtigheid gebruik word by pasiënte met bilièr obstruktiewe versteurings. **VALHEFT** word nie aanbeveel vir gebruik by pasiënte met erge hepatiese belemmering nie.

Hiperkalemie:
Aangesien hiperkalemie kan voorkom, moet die serumkonsentrasies van kalium veral by bejaarde pasiënte en pasiënte met renale belemmering gemonitor word en die gepaardgaande gebruik van kaliumsparende diuretika moet oor die algemeen vermy word (sien **KONTRA-INDIKASIES** en **INTERAKSIES**).

Hartversaking:
Die gebruik van **VALHEFT** by pasiënte met hartversaking veroorsaak gewoonlik 'n mate van verlaging van bloeddruk, maar staking van **VALHEFT** terapie weens volgehoue simptomatiese hipotensie is gewoonlik nie nodig nie, mits doseringsinstruksies gevolg word. Wees versigtig wanneer terapie begin word by pasiënte met hartversaking (sien **DOSIS EN GEBRUIKSAANWYSINGS**).
By pasiënte met hartversaking, moet versigtigheid aan die dag gelê word met gepaardgaande toediening van ACE-inhibeerders, beta-blokkers en **VALHEFT**, aangesien 'n toename in mortaliteit met hierdie drievoudige terapie gerapporteer is (sien **INTERAKSIES**).

Dubbele blokkade van die renien-angiotensien-aldosteroonstelsel (RAAS):
Daar is bewyse dat die gelyktydige gebruik van ACE-inhibeerders, angiotensien II reseptorblokkeerders (ARB's) of aliskiren die risiko vir hipotensie, hiperkalemie en verminderde nierfunksie (insluitend akute nierversaking) mag verhoog. Dubbele blokkade van RAAS deur die gesamentlike gebruik van **VALHEFT** en aliskiren is gevolglik teenaangedui (sien **KONTRA-INDIKASIES** en **INTERAKSIES**).
VALHEFT moet nie saam met aliskiren gebruik word nie (sien **KONTRA-INDIKASIES**).
By pasiënte met erge hartversaking wie se nierfunksie mag afhang van die aktiwiteit van die RAAS, is behandeling met ACE-inhibeerders of angiotensienreseptorantagoniste geassosieer met oligurie en/of progressiewe uremie en met akute nierversaking en/of sterfte. Evaluering van pasiënte met hartversaking moet altyd assessering van nierfunksie insluit.

Invloed op die vermoë om te bestuur en masjiene te gebruik:
Dit is raadsaam om versigtig te wees wanneer bestuur word, masjinerie hanteer word of take verrig word wat konsentrasie vereis, totdat bekend is wat die uitwerking van **VALHEFT** is.

Bevat suiker (anhidriese laktose):
Pasiënte met die skaars oorerflike toestande van laktose- of galaktose-onverdraagsaamheid, bv. galaktosemie, Laplander-laktasetekort, of glukose-galaktosewanabsorpsie moenie **VALHEFT** neem nie.

INTERAKSIES
- Data van kliniese proewe het getoon dat dubbele blokkade van die renien-angiotensien-aldosteroon-stelsel (RAAS) deur gepaardgaande gebruik van ACE-inhibeerders, angiotensien II reseptorblokkers of aliskiren, geassosieer word met 'n hoër frekwensie van ongunstige effekte, soos hipotensie, hiperkalemie en verminderde nierfunksie (sien **KONTRA-INDIKASIES, WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).
- Gepaardgaande gebruik van kaliumbesparende diuretika, kaliumaanvullings of soutplaasvervangers wat kalium bevat, mag lei tot verhoogde serumkalium en by pasiënte met hartversaking tot verhoogde kreatinienvlakke in die serum (sien **KONTRA-INDIKASIES**).
- Aangesien **VALHEFT** nie beduidend gemetaboliseer word nie, word interaksies wat klinies van belang is in die vorm van metaboliese indusering of inhibisie van die sitochroom P450 isoënsiemstelsel, nie verwag nie.
- Die antihipertensiewe effekte van **VALHEFT** mag versterk word deur medisynes wat die bloeddruk verlaag.
- 'n Toename in mortaliteit is met valsartaan gerapporteer by pasiënte met hartversaking wat ook beide ACE-inhibeerders én beta-blokkers ontvang en dit moet vermy word by hierdie pasiënte (sien **WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS**).
- Gepaardgaande gebruik van **VALHEFT** met litium mag die opruiming van litium verlaag en litiumtoksisiteit veroorsaak. Die vlakke van die litium moet gereeld gemonitor word (sien **KONTRA-INDIKASIES**).
- Niesteroïdale anti-inflammatoriese medisyne (NSAIM's), insluitende siklo-oksigenase-2 inhibeerders, mag die effek van diuretika en die antihipertensiewe effek van **VALHEFT** verminder. Pasiënte wat NSAIM's terselfdertyd as **VALHEFT** neem, moet voldoende gehidreer wees en nierfunksie moet gemonitor word.
- Daar is geen klinies beduidende interaksies waargeneem tydens kliniese proewe met die volgende verbindings nie: simetidien, warfarien, furosemied, digoksien, atenolol, indometasien, hidrochloortiasied, amlodipien en glibenklamied.

SWANGERSKAP EN BORSVOEDING
Swangerskap:
Veiligheid is nie bepaal nie. **VALHEFT** moenie tydens swangerskap gebruik word nie (sien **KONTRA-INDIKASIES**). Medisynes wat die renien-angiotensienstelsel affekteer, soos **VALHEFT**, kan embrionale toksisiteit, fetale en neonatale morbiditeit en mortaliteit veroorsaak, wanneer dit aan swanger vrouens toegedien word. Wanneer swangerskap beplan of bevestig word, moet die gebruik van **VALHEFT** so gou as moontlik gestaak word.
Vrouens wat nog kan kinders hê, moet seker maak dat hulle effektiewe voorbehoeding gebruik.

Borsvoeding:
Veiligheid is nie bepaal nie. **VALHEFT** moenie tydens borsvoeding gebruik word nie (sien **KONTRA-INDIKASIES**).

DOSIS EN GEBRUIKSAANWYSINGS
VALHEFT kan met of sonder voedsel geneem word.

Hipertensie:
Die aanbevole dosis **VALHEFT** is 80 mg of 160 mg een keer daagliks, ongeag van ras, ouderdom of geslag.
Die antihipertensiewe effek is grootliks teenwoordig binne 2 weke en maksimale effekte word na 4 weke gesien. By pasiënte wie se bloeddruk nie voldoende beheer word nie, kan die daaglikse dosis tot 320 mg verhoog word, of 'n diuretikum kan saam toegedien word.
VALHEFT mag ook saam met ander antihipertensiewe medisynes toegedien word.

Hartversaking:
Die aanbevole aanvangsdosis van **VALHEFT** is 40 mg twee keer daagliks. Opwaartse titrasie tot 80 mg en 160 mg twee keer daagliks moet gemaak word tot die hoogste dosis wat deur die pasiënt verdra kan word. Dit moet oorweeg word om die dosis van gepaardgaande diuretika te verlaag. Die maksimum daaglikse dosis is 320 mg in verdeelde dosisse toegedien.
Evaluering van pasiënte met hartversaking moet altyd assessering van nierfunksie insluit.

NOTA vir alle indikasies:
Geen aanvanklike dosisaanpassings is nodig vir pasiënte met geringe renale belemmering (waar die kreatinienopruiming bo 70 ml/min is) of vir pasiënte met hepatiese ontoereikendheid van nie-bilière oorsprong en sonder cholestase nie.

VALHEFT word teenaangedui by pasiënte met erge renale belemmering.

Gebruik by kinders en adolessente:
Die veiligheid en doelmatigheid van **VALHEFT** is nie by kinders en adolessente (jonger as 18 jaar) bepaal nie.

NEWE EFFEKTE
Infeksies en infestasies:
Dikwels: virusinfeksies
Minder dikwels: boonstelugweginfeksie, faringitis, sinusitis, rinitis

Bloed- en limfstelselversteurings:
Dikwels: neutropenie
Minder dikwels: trombositopenie

Immuunstelselversteurings:
Minder dikwels: hipersensitiwiteit insluitende serumsiekte

Metabolisme en voedingsteurings:
Minder dikwels: hiperkalemie

Psigiatriese steurings:
Minder dikwels: slaaploosheid, verlaagde libido

Senuweestelselversteurings:
Dikwels: posturale duiseligheid
Minder dikwels: floutes, duiseligheid, hoofpyn

Oogversteurings:
Minder dikwels: wasige visie

Oor- en labirintversteurings:
Minder dikwels: vertigo (draaiduiseling)

Kardiale versteurings:
Minder dikwels: hartversaking

Vaskulêre versteurings:
Dikwels: posturale (ortostatiese) hipotensie
Minder dikwels: hipotensie (mag voorkom by pasiënte met volume-uitputting), vaskulitis

Respiratoriese, torakale en mediastinale versteurings:
Minder dikwels: hoes

Gastro-intestinale versteurings:
Minder dikwels: diarree, buikpyn, naarheid

Hepatobilière versteurings:
Frekwenskie onbekend: hepatitis

Vel- en subkutane weefselversteurings:
Minder dikwels: angio-edeem, uitslag, pruritus, urtikarie

Muskuloskeletale, bindweefsel- en skeletbeenversteurings:
Minder dikwels: rugpyn, artralgie, mialgie, rabdomiolise

Nier- en urienwegversteurings:
Minder dikwels: renale belemmering, akute nierversaking, renale ontoereikendheid

Algemene versteurings en toestande by die plek van toediening:
Minder dikwels: moegheid, astenie, edeem
Frekwenskie onbekend: alopesie

Ondersoeke:
Minder dikwels: Verhoogde lewerensieme. Verlaag: hemoglobien, hematokrit, witbloedselle; verhoog: serumkreatinien, kalium, totale bilirubien.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN
Simptome:
Oordosering met **VALHEFT** mag beduidende hipotensie veroorsaak, wat tot verlaagde bewussynsvlak, sirkulatoriese ineenstorting en/of skok kan lei. Bradikardie of tagikardie kan ook met **VALHEFT** oordosis voorkom.

Behandeling:
Indien ingestie onlangs was, moet braking geïnduseer word. Andersins is die gewone behandeling intraveneuse infusie van fisiologiese soutoplossing. Dit is onwaarskynlik dat dit deur hemodialise verwyder sal word.

IDENTIFIKASIE
VALHEFT 40: Geel, ronde, bikonvekse, filmbedekte tablette met 'J' aan die een kant en '40' aan die ander kant ingepers.
VALHEFT 80: Perskekleurige, ronde, bikonvekse, filmbedekte tablette, gekeep aan die een kant en met '80' aan die gekeepte kant en 'J' aan die ander kant ingepers.
VALHEFT 160: Geel, ovaalvormige, bikonvekse, filmbedekte tablette, gekeep aan die een kant en met '160' aan die gekeepte kant en 'J' aan die ander kant ingepers.

AANBIEDING
3 x stulpstroke wat elk 10 tablette bevat word in 'n buitenste karton verpak (30 tablette per pak). Die stulpstroke bestaan uit aluminiumfoelie en 'n multilaag-basisfilm (OPA/aluminiumfoelie/PVC).

BERGINGSINSTRUKSIES
Bêre by of onder 25 °C.
Hou die stulpstroke in die buitenste karton tot benodig vir gebruik.
HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMERS
VALHEFT 40: 46/7.1.3/0743
VALHEFT 80: 46/7.1.3/0744
VALHEFT 160: 46/7.1.3/0745

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT
LeBasi Pharmaceuticals BK
Jankragebou, 2de Vloer
O.R. Tambostraat 3
Potchefstroom 2531

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Pasiëntinligtingsblad vir VALHEFT 40, 80 en 160

SKEDULERINGSTATUS
Skedule 3

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM
VALHEFT 40 filmbedekte tablet
VALHEFT 80 filmbedekte tablet
VALHEFT 160 filmbedekte tablet

Lees hierdie hele inligtingsblad noukeurig deur, voordat u begin om VALHEFT te neem.
- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Indien u enige verdere vrae het, vra asseblief u dokter of apteker.
- **VALHEFT** is vir u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al het hulle dieselfde simptome as u.

1. WAT VALHEFT BEVAT
Aktiewe bestanddeel: Elke filmbedekte tablet bevat 40 mg, 80 mg of 160 mg valsartaan onderskeidelik.

Die ander bestanddele is anhidriese laktose, krospovidoon, magnesiumstearaat, mikrokristallyne sellulose en silika.
VALHEFT 40 en **160** bevat ook Opadry Yellow (bestaande uit hipromellose, makrogol, titaandioksied en geel ysteroksied) en **VALHEFT 80** bevat ook Opadry Pink (bestaande uit hipromellose, makrogol, titaandioksied, rooi ysteroksied en geel ysteroksied).
Bevat suiker:
Elke **VALHEFT 40** tablet bevat 51,3 mg laktose.
Elke **VALHEFT 80** tablet bevat 102,5 mg laktose.
Elke **VALHEFT 160** tablet bevat 205 mg laktose.

2. WAARVOOR VALHEFT GEBRUIK WORD
Valsartaan help om bloedvate te ontspan en verlig sodoende stremming op die hart.
- **VALHEFT** word gebruik om hoë bloeddruk (hipertensie) te behandel.
- **VALHEFT** word gebruik om simptomatiese hartversaking te behandel.

3. VOORDAT U VALHEFT NEEM
Moenie VALHEFT neem nie:
- Indien u allergies (hipersensitief) is vir valsartaan of vir enige van die ander bestanddele van **VALHEFT** (kyk **WAT VALHEFT BEVAT**).
- Indien u swanger is of u baba borsvoed (sien **Swangerskap en borsvoeding**).
- Indien u nierfunksie belemmer is.
- Indien u voorheen angio-edeem (swelling van u gesig, lippe, mond, tong of keel met of sonder probleme om te sluk of asem te haal) ondervind het terwyl u 'n angiotensien-omsettingsensieminhibeerder (AOE-inhibeerder) of 'n angiotensienreseptorblokker, soos **VALHEFT**, geneem het.
- Indien u hipertrofiese obstruktiewe kardiomiopatie het, 'n ernstige hartversteuring waar die hartspiere verdik is en met normale bloedvloei inmeng.
- Indien u bloedvate na albei niere of na 'n enkele funksionele nier vernou is.
- Indien u aortastenose het, 'n vernouing van die aortaklepopening tussen die linkerventrikel (groot pompkamer van u hart) en die aorta (die hoofslagaar wat bloed weglei van die hart af).
- Indien u diuretika (waterpille) soos spiroonlaktoon, triamtereen of amiloried neem, wat veroorsaak dat u liggaam kalium terughou.
- Indien u aan porfirie ly ('n metaboliese steuring).
- Indien u litium neem (gebruik om sommige gemoedsteurings te behandel).
- Indien u produkte gebruik wat aliskiren bevat (gebruik om hoë bloeddruk te behandel).

Neem spesiale sorg met VALHEFT:
- Lae bloeddruk (simptomatiese hipotensie) sal waarskynlik voorkom indien u gedehidreer is (oormatige verlies aan liggaamsvloeistof) of souttekorte het weens terapie met diuretika (waterpille), beperkte-soutdieet, diarree, of braking. Die water- en elektrolietbalans in u liggaam moet reggestel word voordat u behandeling met **VALHEFT** begin.
- Indien u 'n ernstige niersiekte het.
- Indien u 'n lewerversteuring het waar galvloei blokkeer word.
- Indien u verhoogde kaliumvlakke in u bloed het. Kaliumbesparende diuretika moet vermy word.
- Indien u 'n bejaarde pasiënt is.

Die neem van VALHEFT met kos en drinkgoed:
VALHEFT kan met of sonder voedsel geneem word.

Swangerskap en borsvoeding:
Indien u swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgdeskundige voordat u **VALHEFT** neem.
MOENIE **VALHEFT** tablette neem indien u swanger is, vermoed dat u swanger is of beplan om swanger te raak nie.
MOENIE **VALHEFT** tablette neem indien u u baba borsvoed nie.
Indien u 'n vrou is wat nog kan swanger raak, moet u effektiewe voorbehoeding gebruik.

Bestuur en die gebruik van masjinerie:
VALHEFT mag duiseligheid veroorsaak en u vermoë om 'n voertuig te bestuur of masjinerie te gebruik belemmer. Wees versigtig voordat u take uitvoer wat konsentrasie verg, totdat u weet hoe **VALHEFT** u sal beïnvloed.

Belangrike inligting oor sommige van die bestanddele van VALHEFT:
VALHEFT bevat 'n suiker genaamd anhidriese laktose. Pasiënte met skaars oorerflike toestande van galaktose-onverdraagsaamheid of glukose-galaktosewanabsorpsie, moenie **VALHEFT** neem nie.

Die gebruik van ander medisynes saam met VALHEFT:
Sê altyd vir u gesondheidsorgdeskundige indien u enige ander medisyne neem. (Dit sluit aanvullende of tradisionele medisynes in.)
Sê vir u dokter of apteker indien u tans die volgende gebruik:
- Ander medisynes wat bloeddruk verlaag, veral waterpille (diuretika) of aliskiren.
- Medisynes wat die hoeveelheid kalium in u bloed verhoog. Dit sluit kaliumaanvullings of soutplaasvervangers wat kalium bevat, en kaliumbesparende medisynes in.
- Litium, 'n medisyne wat gebruik word om sommige tipes gemoedsteurings te behandel.
- Niesteroïdale anti-inflammatoriese medisynes (NSAIM's), bv. aspirien of indometasien.
- Indien u behandel word vir hartversaking, word 'n drievoudige kombinasie met AOE-inhibeerders en beta-blokkers nie aanbeveel nie.

Indien u 'n operasie moet ondergaan, lig die narkotiseur of die mediese personeel in dat u **VALHEFT** tablette neem.

4. HOE OM VALHEFT TE NEEM
Moenie medisyne wat vir u voorgeskryf is, met enigiemand anders deel nie.
Neem **VALHEFT** altyd presies soos wat u dokter voorgeskryf het.
Die gewone dosis is 40 mg, 80 mg of 160 mg een keer daagliks.
U dokter kan verskillende dosisse voorskryf, afhangende van u toestand. U moet met u dokter of apteker kontroleer indien u onseker is.
Hierdie tablette moet op omtrent dieselfde tyd elke dag geneem word.
Moenie u behandeling voortydig staak nie, want u siekte mag vererger.
Indien u die indruk kry dat die uitwerking van **VALHEFT** te sterk of te swak is, sê dit vir u dokter of apteker.

Indien u meer VALHEFT geneem het as wat u behoort:
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
Neem hierdie inligtingsblad en die oorblywende **VALHEFT** tablette saam met u sodat die dokter kan sien wat u geneem het. U mag erge duiseligheid en/of floutes ervaar, sowel as 'n stadiger of vinniger polsspoed.

Indien u vergeet om VALHEFT te neem:
Indien u u dosis met slegs 'n paar uur gemis het, neem die oorgeslane dosis sodra u onthou. Indien dit byna tyd is vir u volgende dosis, slaan die dosis wat vergeet is oor en neem **VALHEFT** op die gewone geskeduleerde tyd.
Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat oorgeslaan is nie.

5. MOONTLIKE NEWE-EFFEKTE
VALHEFT kan newe-effekte hê.
Nie alle newe-effekte wat vir **VALHEFT** gerapporteer is, word in hierdie inligtingsblad ingesluit nie.

Indien u algemene gesondheid agteruitgaan of indien u enige ongewenste effekte ervaar terwyl **VALHEFT** geneem word, konsulteer asseblief u dokter, apteker of ander gesondheidsorgdeskundige.
Indien enige van die volgende gebeur, hou op om **VALHEFT** te neem en sê onmiddellik vir u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal:
- Swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik kan maak om te sluk of asem te haal.
- Uitslag of gejeuk.
- Floutes.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, mag u 'n ernstige allergiese reaksie op **VALHEFT** gehad het. U mag dringende mediese sorg of hospitalisasie nodig hê.

Sê onmiddellik vir u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
Newe-effekte wat dikwels mag voorkom:
- U kry dikwels infeksies weens 'n gebrek aan witbloedselle.
- Virusinfeksies.

Newe-effekte wat minder dikwels mag voorkom:
- U bloedvate raak ontsteek, hartprobleme.
- Swelling van u liggaam (edeem).
- U kry infeksie in u lugweë.
- Diarree, maagpyn, naarheid.
- Wasige visie.
- Spierteerheid of -swakheid (mialgie), pynlike, geswolle gewrigte (artralgie).
- U bloei of kneus makliker as normaalweg weens 'n vermindering in die aantal bloedplaatjies.
- U voel moeg en lyk bleek, omdat daar minder rooibloedselle in u bloed is.
- Verhoogde kaliumvlakke in u bloed.
- Daar is 'n probleem met die werking van u lewer of niere.

Newe-effekte wat met onbekende frekwensie voorkom:
- Lewersiekte met naarheid, braking, koors, vergeling van die vel en die wit van die oë (hepatitis).

Hierdie is almal ernstige newe-effekte. U mag dringende mediese aandag nodig hê.

Sê so gou as moontlik vir u dokter indien u enige van die volgende opmerk:
Newe-effekte wat dikwels mag voorkom:
- Duiseligheid, lighoofdigheid (veral wanneer u regop kom uit 'n sittende of lêende posisie).
- Veluitslag.

Newe-effekte wat minder dikwels mag voorkom:
- Lae bloeddruk, slaapprobleme.
- Hoes, toe neus, sinusontsteking, seer keel.
- Vermoeidheid, ongewone moegheid, verlaagde libido.
- Hoofpyn, 'n draaigevoel in u kop.
- Verhoogde kaliumvlakke in u bloed, styging in lewerensieme.

Newe-effekte wat met onbekende frekwensie voorkom:
- Haarverlies.

Indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, lig asseblief u dokter of apteker in.

6. BERGING EN WEGDOENING VAN VALHEFT
- Bêre by of onder 25 °C.
- Hou die stulpstroke in die buitenste karton tot nodig vir gebruik.
- STOOR ALLE MEDISYNES BUITE BEREIK VAN KINDERS.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

7. AANBIEDING VAN VALHEFT
3 x stulpstroke wat elk 10 tablette bevat word in 'n buitenste karton verpak (30 tablette per pak). Die stulpstroke bestaan uit aluminiumfoelie en 'n multilaag-basisfilm (OPA/aluminiumfoelie/PVC).

8. IDENTIFIKASIE VAN VALHEFT
VALHEFT 40: Geel, ronde, bikonvekse, filmbedekte tablette met 'J' aan die een kant en '40' aan die ander kant ingepers.
VALHEFT 80: Perskekleurige, ronde, bikonvekse, filmbedekte tablette, gekeep aan die een kant en met '80' aan die gekeepte kant en 'J' aan die ander kant ingepers.
VALHEFT 160: Geel, ovaalvormige, bikonvekse, filmbedekte tablette, gekeep aan die een kant en met '160' aan die gekeepte kant en 'J' aan die ander kant ingepers.

9. REGISTRASIENOMMERS
VALHEFT 40: 46/7.1.3/0743
VALHEFT 80: 46/7.1.3/0744
VALHEFT 160: 46/7.1.3/0745

10. NAAM EN ADRES VAN DIE REGISTRASIEHOUER
LeBasi Pharmaceuticals BK
Jankragebou, 2de Vloer
O.R. Tambostraat 3
Potchefstroom 2531
Tel. nr.: 018 297 4059

11. PUBLIKASIEDATUM
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