Front Side

280 mm

335 mm

HYLOKAT TABLETS
PM03923602

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

HYLOKAT 50/12.5 (tablets)
Losartan potassium 50 mg and hydrochlorothiazide 12.5 mg
Contains sugar (62.5 mg lactose monohydrate)

HYLOKAT 100/25 (tablets)
Losartan potassium 100 mg and hydrochlorothiazide 25 mg
Contains sugar (125 mg lactose monohydrate)

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

What is in this leaflet?

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

1. What HYLOKAT is and what it is used for

HYLOKAT is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Losartan and hydrochlorothiazide work together to lower high blood pressure. Your doctor has prescribed **HYLOKAT** because you have condition known as hypertension or high blood pressure.

2. What you need to know before you take or give HYLOKAT

Do not take or give HYLOKAT:
- If you are hypersensitive (allergic) to losartan or hydrochlorothiazide or any of the other ingredients of **HYLOKAT** (listed in section 6).
- If you have previously been treated with a medication in the same group of medicines as **HYLOKAT** (angiotensin receptor antagonists) or with a medication in the group of medicines known as ACE inhibitors and have had allergic reactions with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing.
- If you have hereditary or idiopathic angioedema, a type of swelling that can occur anywhere on the body, but most frequently appears around the lips and eyes. Less commonly, the tongue or the mucous membranes of the throat and the mouth can swell - which, if severe, can be life-threatening.
- If you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart.
- If you have severe kidney disease.
- If you have narrowing of the blood vessels to both kidneys or to a single kidney.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart).
- If you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- If you have porphyria (a group of rare inherited blood disorders).
- Thiazide water tablets in (fixed dose) combination as with **HYLOKAT** should not be given to patients with Addison's disease (an uncommon disorder that occurs when your body does not produce enough cortisol, a hormone). This therapy should also not be used in patients with severe kidney disease or patients not passing urine, and in patients who show allergy to other sulphonamide-derived medicines (ask your doctor if you are not sure what sulphonamide-derived medicines are).
- Lithium therapy: Concomitant administration with **HYLOKAT** may lead to toxic blood concentrations of lithium.
- If you are pregnant or breastfeeding (see Pregnancy and Breastfeeding).
- If you have liver disease.
- If you have impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you have kidney damage and/or taking antibiotic medicines that belong to the class Fluoroquinolones (see section Other medicines and **HYLOKAT**).

Warnings and precautions
Take special care with **HYLOKAT**:
- If you are pregnant or planning to fall pregnant
- If you have or have had medical problems, any allergies, or if you have recently suffered from vomiting or diarrhoea.
- If you have any liver or kidney problems, gout, sugar diabetes, lupus erythematosus, or if you are being treated with diuretics (water tablets). In these cases, your doctor may need to adjust the dose of your medication.
- Before surgery and any anaesthesia (even at a dentist's office), tell the doctor or dentist that you are taking **HYLOKAT**, as there may be a sudden fall in blood pressure associated with the anaesthetic.
- If you are taking lithium (a medicine used to treat a certain kind of depression).
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren, an ACE inhibitor (e.g. enalapril, lisinopril, ramipril).
- Inform your doctor immediately if you are taking any antibiotic medicines which belong to the group Fluoroquinolones (e.g. ciprofloxacin, levofloxacin, moxifloxacin). Use of ACE inhibitors / renin-angiotensin receptor blockers, including LOSARTAN MACLEODS, together with fluoroquinolones can cause damage to your kidneys.

Use in children
- As there is no experience with the use of **HYLOKAT** in children, **HYLOKAT** should not be given to children.

Other medicines and HYLOKAT
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
It is especially important for your doctor to know if you are taking other medicines to reduce blood pressure, other diuretics (water tablets), medications to treat diabetes including insulin, resins which reduce high cholesterol, muscle relaxants, pressor amines such as adrenaline, steroids, certain pain and arthritis medicines, or lithium (a medicine used to treat a certain kind of depression).
Sedatives, tranquillizers, narcotics, alcohol and analgesics may increase the blood pressure-lowering effect of **HYLOKAT**, so tell your doctor if you take any of these medicines.
Tell your doctor if you are taking blood pressure lowering medicine containing aliskiren, an ACE inhibitor (e.g. enalapril, lisinopril, ramipril).
Tell your doctor if you are taking medicines used to treat infections (antibiotic medicines) which belong to the group fluoroquinolones (e.g. levofloxacin, moxifloxacin, ciprofloxacin)

HYLOKAT with food and drink:
HYLOKAT can be taken with or without food. For convenience and to help you remember, try to take **HYLOKAT** at the same time each day.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby please consult your doctor, pharmacist or other healthcare professional for advice before taking **HYLOKAT**.
- You should not use **HYLOKAT** while you are pregnant or breastfeeding your baby, as **HYLOKAT** may harm your baby. If you are pregnant or become pregnant while taking **HYLOKAT**, stop taking **HYLOKAT** and tell your doctor immediately.

Driving and using machines
You should be careful in performing tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate **HYLOKAT**.

HYLOKAT contains
HYLOKAT contains sugar (lactose monohydrate).
If you have been told by our doctor that you have an intolerance to some sugars, contact your doctor before taking **HYLOKAT**.

3. How to take HYLOKAT

Do not share medicines prescribed for you with any other person.
Always take or give **HYLOKAT** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
If you have the impression that the effect of **HYLOKAT** is too strong or too weak, talk to your doctor or pharmacist.

The usual dose is:
The usual dose of **HYLOKAT** is 1 tablet of **HYLOKAT** per day.
It is important to continue taking **HYLOKAT** for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

If you take more HYLOKAT than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
- In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdose can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take HYLOKAT
If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you stop taking HYLOKAT
If treatment with **HYLOKAT** is stopped earlier than your doctor has prescribed, the symptoms may come back. Always complete the course that your doctor prescribed.

4. Possible side effects

HYLOKAT can have side effects.
Not all the side effects reported for **HYLOKAT** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **HYLOKAT**, please consult your doctor, pharmacist or healthcare professional for advice.

If any of the following happens, stop taking HYLOKAT and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **HYLOKAT**. You may need urgent medical attention or hospitalization.

Tell your doctor if you notice any of the following:
Frequent side effects:
- Dizziness, Headache
- Asthenia/fatigue (tiredness), oedema/swelling, chest pain
- Upper respiratory infection (chest infection)
- Inability to sleep (Insomnia)
- Palpitation, tachycardia (irregular heartbeat)
- Cough, pharyngitis, nasal congestion, sinus disorder, sinusitis, upper respiratory infection
- Diarrhoea, nausea, abdominal pain, dyspepsia (indigestion)
- Back pain, muscle cramps, leg pain, muscle pain (myalgia)
- kidney problems (you may experience tiredness, itching, unexplained weight loss, insufficient urine production, swelling)
- Hyperkalaemia, elevations of ALT, mild reduction of haematocrit and haemoglobin, too low sugar in the blood (hypoglycaemia). (you may experience shakiness, dizziness, hunger, sweating)

Less frequent side effects:
- Lack of healthy red blood cells (anaemia), (you may notice tiredness, dizziness, headache, pale color);
- Disease of the skin, mucous membranes, and sometimes other organs that most commonly affects children (Henoch Schönlein purpura),
- a discoloration of the skin resulting from bleeding underneath (ecchymosis),
- the rupture or destruction of red blood cells. (haemolysis), (you may notice abnormal paleness, yellowish skin, eyes, mouth, fever, weakness, dizziness)
- low blood platelet count(thrombocytopenia) (you may notice bleeding gums, black stools, tiny red or purple dots on the lower legs that appear as a rash)
- A low white blood cell count (leukopenia) (you may notice fever, chills sweating, increase in infections)
- Severe lowered white blood cell count (agranulocytosis), (you may notice fever, chills, fast heart beat, sore mouth, throat and bleeding gums)
- haemolytic anaemia, aplastic anaemia, (you may experience headache, dizziness, shortness of breath, bruising, tiredness, black in stools)
- blood spots on the skin (purpura)
- nervousness,
- burning or prickling sensation that is usually felt in the hands, arms, legs, or feet (paraesthesia),
- Weakness, numbness and pain from nerve damage, usually in the hands and feet. (peripheral neuropathy),
- Tremor (shakes), migraine, syncope (fainting)
- Low blood pressure (hypotension),
- orthostatic hypotension (A form of low blood pressure that happens when standing up from sitting or lying down).,
- sternalgia (Pain around the sternum)
- chest pain (angina pectoris),
- grade II-AV block (you may experience dizziness, fainting, nausea, shortness of breath, fatigue)
- cerebrovascular event, (you will experience sudden numbness or weakness in the face, arm or leg, especially on one side of the body, sudden confusion, trouble speaking, trouble seeing or walking, dizziness, loss of balance and lack of co-ordination).
- heart attack (myocardial infarction),
- arrhythmias - problem with the rate or rhythm of your heartbeat (atrial fibrillations, sinus bradycardia, ventricular tachycardia, ventricular fibrillation)
- sudden spinning sensation (vertigo), ringing in the ears (tinnitus)
- blurred vision, burning/stinging in the eye, conjunctivitis, decrease in visual acuity, xanthopsia (colour vision deficiency)
- Inflammation of the blood vessels (vasculitis), necrotizing angiitis (you will notice pain, numbness, tingling in arm or leg, weakness in arm or leg, different sizes of pupil, eyelid drooping, difficulty swallowing, impaired speech and difficulty moving)
- pharyngeal discomfort, laryngitis, difficulty breathing (dyspnea), bronchitis, nose bleeds (epistaxis), rhinitis, respiratory congestion, Respiratory distress including pneumonitis and pulmonary oedema
- constipation, dental pain, dry mouth, flatulence, gastritis, vomiting, obstipation, nausea, diarrhoea, swollen pancreas (pancreatitis), infection of the salivary glands (sialoadenitis), spasms
- hypersensitivity (you may experience a skin rash, hives, itching, fever, swelling, shortness of breath, wheezing and runny nose)
- anorexia (an eating disorder), gout, hyperuricaemia (increased uric acid), hyperglycaemia (increased sugar levels), hypokalaemia (decreased potassium levels), hyponatraemia (low sodium levels)
- Rash, alopecia, dermatitis, dry skin, erythema, flushing, photosensitivity, itching of the skin (pruritus), hives sweating
- arm pain, joint swelling, knee pain, musculoskeletal pain, shoulder pain, stiffness, joint pain (arthralgia), arthritis, pain in the hip (coxalgia), muscle weakness
- excessive urination at night (nocturia), urinary frequency, urinary tract infection, glycosuria, interstitial nephritis (kidney disorder), kidney dysfunction, kidney failure
- decreased libido, erectile dysfunction/impotence
- mild increase in urea and creatinine serum levels, increase in liver enzymes and bilirubin
- Jaundice (yellowing of the eyes and skin), inflammation of the pancreas

Frequency unknown side effects:
- anxiety disorder, panic disorder, confusion, depression, abnormal dreams, sleep disorder, somnolence, memory impairment
- liver function abnormalities (you may notice skin and eyes that appear yellowish, swelling in legs and ankles, dark colored urine, always tired, nausea and vomiting)
- unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis)
- flu-like symptoms, generally feeling unwell (malaise)
- (low levels of sodium in the blood) hyponatraemia (you will notice headache, confusion, drowsiness, no energy, restlessness)
- cutaneous lupus erythematosus (an autoimmune disease affecting the skin)
- Non-melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma)
- Anaphylactic reactions (you will notice hives, itching, red or pale skin, low blood pressure, trouble breathing, narrowing airway, dizziness)
- Arthralgia (you may notice burning, itching, numbness, pain or tenderness, redness, swelling, stiffness)
- disturbed taste (dysgeusia)

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

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **HYLOKAT**.

5. How to store HYLOKAT

Store at or below 25 °C (room temperature). Protect from light and moisture.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What HYLOKAT contains
The active substance is Losartan potassium 50 mg and hydrochlorothiazide 12,5 mg and Losartan potassium 100 mg and hydrochlorothiazide 25 mg

The other ingredients include colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch and Opadry yellow 20A52135/ Instacoat universal yellow A05G13052.

What HYLOKAT looks like and contents of the pack
HYLOKAT 50/12.5
Yellow coloured, oval shaped, biconvex, film coated tablets having 'ML 43' debossed on one side and plain on other side.
HYLOKAT 100/25
Yellow coloured, oval shaped, biconvex, film coated tablets having 'ML 44' debossed on one side and plain on other side.

Blister pack:
Tablets are packed in cold form laminate, 25 µm OPA/45 µm aluminum foil/60 µm PVC and plain 25 µm aluminum foil/6-8 gsm HSL as the lidding material.
Pack sizes include 10 and 30 tablets.

HDPE container pack:
Round, white, HDPE container 40 cc or 75 cc with 33 mm or 38 mm neck finish, containing 30 or 90 tablets, closed with child resistant closure, with pulp and heat seal liner 33 mm or 38 mm and packed in a pre-printed unit carton.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12.
Alberton, South Africa.

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Registration number
HYLOKAT 50/12.5: 47/7.1.3/0887
HYLOKAT 100/25: 47/7.1.3/0888

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodssaproducts.co.za/ or contact 011 682 1169

Back Side

280 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S3

HYLOKAT 50/12.5 (tablette)
50,0 mg losartankalium en 12,5 mg hidrochloortiasied
Bevat suiker (62,5 mg laktosemonohidraat)

HYLOKAT 100/25 (tablette)
100 mg losartankalium en 25 mg hidrochloortiasied
Bevat suiker (125 mg laktosemonohidraat)

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy HYLOKAT begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **HYLOKAT** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk?
1. Wat **HYLOKAT** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **HYLOKAT** neem
3. Hoe om **HYLOKAT** te neem
4. Moontlike newe-effekte
5. Hoe om **HYLOKAT** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat HYLOKAT is en waarvoor dit gebruik word

HYLOKAT is 'n kombinasie van 'n angiotensien II reseptor antagonis (losartan) en 'n diuretikum (hidrochloortiasied). Losartan en hidrochloortiasied werk saam om hoë bloeddruk te verlaag.
Jou dokter het **HYLOKAT** voorgeskryf omdat jy 'n toestand bekend as hipertensie of hoë bloeddruk het.

2. Wat jy behoort te weet voordat jy HYLOKAT neem

Moet nie HYLOKAT neem nie:
- Indien jy hipersensitief (allergies) vir losartan of hidrochloortiasied of enige van die ander bestanddele van **HYLOKAT** is (gelys in afdeling 6).
- Indien jy voorheen behandel is met 'n middel in dieselfde groep medisyne as **HYLOKAT** (angiotensien reseptor antagoniste) of met 'n middel in die groep medisyne bekend as AOE inhibeerders en jy allergiese reaksies met **swelling** van die gesig, lippe, tong en/of keel, met probleme om te sluk of asem te haal, gehad het.
- Indien jy oorerflike of idiopatiese angioëdeem het, 'n tipe swelling wat enige plek op die liggaam kan voorkom, maar kom die meeste voor rondom die lippe en oë. Minder algemeen kan die tong of die slymvliese van die keel en die mond swel wat, indien ernstig, lewensgevaarlik kan wees.
- Indien jy hipertrofiese obstruktiewe kardiomiopatie het, 'n hartversteuring waarin die wande van die ventrikels (onderste hartkamers) verdik (hipertrofie) en styf word en die verdikte spier die vloei van bloed uit die hart blokkeer.
- Indien jy ernstige niersiekte het.
- Indien jy vermouing van die bloedvate na albei niere of na 'n enkele nier het.
- Indien jy aortastenose het, 'n vermouing van die aortaklep opening tussen die linkerventrikel (groot pompkamer van die hart) en die aorta (die hoofslagaar wat weg van die hart aflei).
- Indien jy diuretika (waterpille) gebruik wat veroorsaak dat jou liggaam kalium terughou, soos spironolaktoon, triamtereen en amiloried.
- Indien jy porfirie het ('n groep seldsame oorgeërfde bloedafwykings).
- Tiasied watertablette in (vaste dosering) kombinasie soos met **HYLOKAT** moet nie aan pasiënte met Addison se siekte gegee word nie ('n ongewone afwyking wat voorkom wanneer jou liggaam nie genoeg kortisol, 'n hormoon, produseer nie). Hierdie behandeling moet ook nie gebruik word in pasiënte met ernstige niersiekte of pasiënte wat nie urineer nie, en in pasiënte wat allergie toon vir ander sulfonamied-afgeleide medisyne (vra jou dokter indien jy nie seker is wat sulfoonamied-afgeleide medisyne is nie).
- Litium behandeling: Gelyktydige toediening met **HYLOKAT** kan lei tot toksiese bloedkonsentrasies van litium.
- Indien jy swanger is of borsvoed (sien Swangerskap en Borsvoeding).
- Indien jy 'n lewersiekte het.
- Indien jy verswakte nierfunksie het en jy behandel word met 'n bloeddrukverlagende middel wat aliskiren bevat.
- Indien jy nierskade het en/of antibiotika neem wat aan die klas Fluorokinolone behoort (sien afdeling Ander medisyne en **HYLOKAT**).

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met **HYLOKAT:**
- Indien jy swanger is of beplan om swanger te raak.
- Indien jy mediese probleme het, of gehad het, enige allergieë, of indien jy onlangs aan braking of diarree gely het.
- Indien jy enige lewer- of nierprobleme, jig, suikerdiabetes, lupus eritemateuses het, of as jy met diuretika (watertablette) behandel word. In hierdie gevalle sal jou dokter dalk die dosis van jou medikasie moet aanpas.
- Voor chirurgie en enige narkose (selfs by 'n tandarts se spreekkamer), vertel die dokter of tandarts dat jy **HYLOKAT** neem, aangesien daar 'n skielike daling in bloeddruk kan wees wat met verband hou met die narkose.
- Indien jy litium gebruik ('n medisyne wat gebruik word om 'n sekere soort depressie te behandel).
- Indien jy diabetes of ingekorte nierfunksie het en jy behandel word met 'n bloeddrukverlagende middel wat aliskiren, 'n AOE inhibeerder (bv. enalapril, lisinopril, ramipril) bevat.
- Stel jou dokter onmiddellik in kennis indien jy enige antibiotika neem wat aan die groep Fluorokinolone behoort (bv. siprofloksasien, levofloksasien, moksifloksasien). Gebruik van AOE inhibeerders/renien angiotensien reseptor blokkeerders, insluitend LOSARTAN MACLEODS, tesame met fluorokinolone kan skade aan jou niere veroorsaak.

Gebruik in kinders
- Aangesien daar geen ondervinding is met die gebruik van **HYLOKAT** in kinders nie, moet **HYLOKAT** nie aan kinders gegee word nie.

Ander medisyne en HYLOKAT
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).
Dit is veral belangrik vir jou dokter om te weet of jy ander medisyne gebruik om bloeddruk te verlaag, ander diuretika (watertablette), medikasie om diabetes te behandel, insluitend insulien, hersa wat hoë cholesterol verlaag, spierverslappers, druk amiene soos adrenalien, steroïede, sekere pyn- en artritismedisyne, of litium ('n medisyne wat gebruik word om 'n sekere soort depressie te behandel).
Kalmeermiddels, susmiddels, verdowingsmiddels, alkohol en pynstillers kan die bloeddrukverlagende effek van **HYLOKAT** verhoog, so vertel jou dokter as jy enige van hierdie middels gebruik.
Vertel jou dokter as jy bloeddrukverlagende medisyne gebruik wat aliskiren, 'n AOE inhibeerder (bv. enalapril, lisinopril, ramipril) bevat.
Vertel jou dokter as jy medisyne neem wat gebruik word om infeksies te behandel (antibiotiese middels) wat aan die groep fluorokinolone behoort (bv. levofloksasien, moksifloksasien, siprofloksasien).

HYLOKAT met kos en vloeistowwe:
HYLOKAT kan met, of sonder kos geneem word. Vir gerief en om jou te help onthou, probeer om **HYLOKAT** elke dag op dieselfde tyd te neem.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **HYLOKAT** neem.
- Jy moet nie **HYLOKAT** gebruik terwyl jy swanger is, of jou baba borsvoed nie, aangesien **HYLOKAT** jou baba kan benadeel. Indien jy swanger is of swanger raak terwyl jy **HYLOKAT** gebruik, hou op om **HYLOKAT** te neem en vertel onmiddellik jou dokter.

Bestuur en gebruik van masjinerie
Jy moet versigtig wees in die uitvoering van take wat spesiale aandag kan verg (byvoorbeeld, 'n motor bestuur of gevaarlike masjinerie hanteer) totdat jy weet hoe jy **HYLOKAT** verdra.

HYLOKAT bevat
HYLOKAT bevat suiker (laktosemonohidraat).
Indien jy deur jou dokter ingelig is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy **HYLOKAT** neem.

3. Hoe om HYLOKAT te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem of gee altyd **HYLOKAT** presies soos jou dokter jou voorgeskryf het. Jy moet jou dokter of apteker raadpleeg indien jy nie seker is nie.
Indien jy die indruk het dat die effek van **HYLOKAT** te sterk of te swak is, praat met jou dokter of apteker.

Die gewone dosis is:
Die gewone dosis **HYLOKAT** is 1 tablet **HYLOKAT** per dag.
Dit is belangrik om aan te hou om **HYLOKAT** te neem vir so lank as wat jou dokter dit voorskryf om goeie beheer van jou bloeddruk te handhaaf.

Indien jy meer HYLOKAT neem as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
- In die geval van 'n oordosering, kontak jou dokter dadelik sodat mediese aandag onmiddellik gegee kan word. Oordosering kan 'n daling in bloeddruk, hartkloppings, stadige polsslag, veranderinge in bloedsamestelling en dehidrasie veroorsaak.

Indien jy vergeet om HYLOKAT te neem
Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou en gaan dan aan soos voorheen. Moet nie 'n dubbele dosis neem om vir oorgeslane individuele doserings op te maak nie

Indien jy staak om HYLOKAT te gebruik
Indien behandeling met **HYLOKAT** vroeër gestaak word as wat jou dokter voorgeskryf het, kan die simptome terugkom. Voltooi altyd die kursus wat jou dokter voorgeskryf het.

4. Moontlike newe-effekte

HYLOKAT kan newe-effekte hê.
Nie al die newe-effekte wat vir **HYLOKAT** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of indien jy enige ongewenste effekte ondervind terwyl jy **HYLOKAT** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, staak die gebruik van HYLOKAT en lig onmiddellik jou dokter in, of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Ernstige allergiese reaksie (uitslag, jeuk, swelling van die gesig, lippe, mond of keel wat dit moeilik kan maak om te sluk of asem te haal).

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige allergiese reaksie op **HYLOKAT** gehad. Jy het moontlik dringende mediese aandag of hospitalisasie nodig.

Vertel jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte:
- Duiseligheid, hoofpyn
- Astenie/vermoeidheid (moegheid), edeem/swelling, borskaspyn
- Boonste lugweginfeksie (borsinfeksie)
- Onvermoë om te slaap (Insomnie)
- Hartklopping, tagikardie (onreëlmatige hartklop)
- Hoes, faringitis, neusverstopping, sinusversteuring, sinusitis, boonste lugweginfeksie
- Diaree, naarheid, abdominale pyn, dispepsie (slegte spysvertering)
- Rugpyn, spierkrampe, beenpyn, spierpyn (mialgie)
- Nierprobleme (jy kan moegheid, jeuk, onverklaarbare gewigsverlies, onvoldoende urienproduksie, swelling ervaar).

Minder gereelde newe-effekte:
- Gebrek aan gesonde rooibloedselle (anemie), (jy kan moegheid, duiseligheid, hoofpyn, bleek kleur opmerk),
- Siekte van die vel, slymvliese, en soms ander organe wat die mees algemeenste kinders affekteer (Henoch Schönlein purpura),
- 'n Verkleuring van die vel as gevolg van bloeding van onder (eggimose),
- Die skeur of vernietiging van rooibloedselle. (hemolise), (jy mag abnormale bleekheid, gelerige vel, oë, mond, koors, swakheid, duiseligheid opmerk),
- Lae bloedplaatjietelling (trombositopenie) (jy mag dalk bloeiende tandvleis, swart stoelgang, klein rooi of pers kolletjies op die onderbene opmerk wat as 'n uitslag voorkom)
- 'n Lae witbloedseltelling (leukopenie) (jy mag dalk koors, koue rillings met sweet, toename in infeksies opmerk),
- Ergo verlaagde witbloedseltelling (agranulositose), (jy mag dalk koors, koue rillings, vinnige hartklop, seer mond, -keel en bloeiende tandvleise opmerk),
- Hemolitiese anemie, aplastiese anemie, (jy kan hoofpyn, duiseligheid, kortasem, kneusing, moegheid, swart in stoelgang ervaar),
- Bloed kolletjies op die vel (purpura),
- Senuweeagtigheid,
- Brandende of prikkelende sensasie wat gewoonlik in die hande, arms, bene of voete gevoel word (parestesie),
- Swakheid, gevoelloosheid en pyn van senuweeskade, gewoonlik in die hande en voete (perifere neuropatie),
- Bewing (rillings), migraine, sinkopee (floute)
- Lae bloeddruk (hipotensie),
- Ortostatiese hipotensie ('n vorm van lae bloeddruk wat voorkom wanneer jy opstaan nadat jy gesit of lê het),
- Sternalgie (pyn rondom die borsbeen),
- Borskaspyn (angina pectoris),
- Graad II-AV-blok (jy kan duiseligheid, floute, naarheid, kortasem, vermoeidheid ervaar),
- Serebrovaskulêre gebeurtenis, (jy sal skielike gevoelloosheid of swakheid in die gesig, arm of been ervaar, veral aan die een kant van die liggaam, skielike verwarring, probleme met praat, probleme om te sien of loop, duiseligheid, verlies aan balans en gebrek aan koördinasie),
- Hartaanval (miokardiale infarksie),
- Aritmieë - probleem met die tempo of ritme van jou hartklop (atriale fibrillasie, sinus bradikardie, ventrikulêre tagikardie, ventrikulêre fibrillasie),
- Skielike draai sensasie (vertigo), gesuis in die ore (tinnitus),
- Dowwe visie, brand/steek in die oog, konjunktivitis, afname in gesigskerpte, xantopsie (gebrek aan kleurvisie),
- Ontsteking van die bloedvate (vaskulitis), nekrotiserende angiitis (jy sal pyn, gevoelloosheid, tinteling in arm of been, swakheid in arm of been, verskillende groottes van pupil, ooglid wat hang, sukkel om te sluk, gebrekkige spraak en bewegingsprobleme opmerk),
- Faringeale ongemak, laringitis, moeilike asemhaling (dispnee), brongitis, neusbloeding (epistakse), rinitis, respiratoriese kongestie, respiratoriese nood insluitend longontsteking en pulmonêre edeem,
- Hardlywigheid, tandpyn, droë mond, winderigheid, gastritis, braking, verstopping, naarheid, diaree, geswelde pankreas (pankreatitis), infeksie van die speekselkliere (sialoadenitis), spasmas,
- Hipersensitiwiteit (jy kan 'n veluitslag, galbulte, jeuk, koors, swelling, kortasem, asemgeflut en loopneus ervaar),
- Anoreksie ('n eetversteuring), jig, hiper urisemie (verhoogde uriensuur), hiperglukemie (verhoogde suikervlakke), hipokalemie (verlaagde kaliumvlakke), hiponatremie (lae natriumvlakke),
- Uitslag, alopesie, dermatitis, droë vel, eriteem, blosing, fotosensitiwiteit, jeuk van die vel (pruritus), galbulte, sweet,
- Armpyn, swelling van gewrigte, knliepyn, muskuloskeletale pyn, skouerpyn, styfheid, gewrigspyn (artralgie), artritis, pyn in die heup (koksalgie), spierswakheid,
- Oormatige urinering snags (nokturie), urinêre frekwensie, urienweginfeksie, glukosurie, interstisiële nefritis (niervversteuring), nierdisfunksie, nierversaking,
- Verminderde libido, erektiele disfunksie/impotensie,
- Ligte toename in ureum en kreatinien serumvlakke, toename in lewerensieme en bilirubien,
- Geelsug (vergeling van die oë en vel), ontsteking van die pankreas.

Newe-effekte met onbekende frekwensie:
- Angsversteuring, paniekversteuring, verwarring, depressie, abnormale drome, slaapversteuring, slaperigheid, geheue inkorting.
- Lewerfunksie-abnormaliteite (jy kan vel en oë sien wat geel lyk, swelling in bene en enkels, donkerkleurige urlene, altyd moeg, naarheid en breking),
- Onverklaarbare spierpyn met donker (tee kleurige) uriene (rabdomiolise),
- Griepagtige simptome, ongesteldheid (malaise),
- (lae vlakke van natrium in die bloed) hiponatremie (jy sal hoofpyn, verwarring, lomerigheid, geen energie, rusteloosheid opmerk),
- Kutaneuse lupus eritemateusus ('n outoimmuun siekte wat die vel aantas),
- Nie-melanoom velkanker (basaalselkarsinoom en skubselkarsinoom),
- Anafilaktiese reaksies (jy sal galbulte, jeuk, rooi of bleek vel, lae bloeddruk, probleme met asemhaling, vermoude lugweg, duiseligheid opmerk),
- Artralgie (jy mag brand, jeuk, gevoelloosheid, pyn of teerheid, rooiheid, swelling, styfheid opmerk),
- Versteurde smaak (disgeusie).

Lig asseblief jou dokter of apteker in indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk genoem is nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting rakende die veiligheid van **HYLOKAT** te verskaf.

5. Hoe om HYLOKAT te bewaar

Bewaar by of benede 25 °C. (kamertemperatuur). Beskerm teen lig en vog.
Bewaar alle medisyne buite bereik van kinders.
Bewaar in die oorspronklike verpakking/houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum, wat aangebring is op die stulpstrook/etiket/karton/bottel, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in die drein of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting

Wat HYLOKAT bevat
Die aktiewe stowwe is 50 mg losartankalium en 12,5 mg hidrochloortiasied en 100 mg losartankalium en 25 mg hidrochloortiasied.

Die ander bestanddele sluit in kolloïdale silikondioksied, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, pregelatiniseerde stysel en Opadry geel 20A52135/ Instacoat universeel geel A05G13052.

Hoe HYLOKAT lyk en inhoud van die verpakking
HYLOKAT 50/12.5
Geel gekleurde, ovaalvormige, bikonvekse filmbedekte tablette met 'ML 43' op een kant gedruk en glad aan die ander kant.
HYLOKAT 100/25
Geel gekleurde, ovaalvormige, bikonvekse filmbedekte tablette met 'ML 44' op een kant gedruk en glad aan die ander kant.

Stulpverpakking:
Tablette word verpak in koue vorm laminaat, 25 µ OPA/45 µm aluminiumfoelie/60 µm PVC en gewone 25 µm aluminiumfoelie/6-8 gsm HSL as die dekmateriaal.
Verpakkingsgroottes sluit 10 en 30 tablette in.

HDPE houer verpakking:
Ronde, wit, 40 cc of 75 cc HDPE houer met 33 mm of 38 mm nek afwerking, bevattende 30 of 90 tablette, gesluit met kinderbestande sluiting, met pulp en hitteseëlvoering 33 mm of 38 mm en verpak in 'n voorafbedrukte buitenste karton.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was hersien in
18 Mei 2022

Registrasienommers
HYLOKAT 50/12.5: 47/7.1.3/0887
HYLOKAT 100/25: 47/7.1.3/0888

Toegang tot die ooreenstemmende professionele inligting
Die ooreenstemmende professionele inligting kan by https://macleodssaproducts.co.za/ verkry word of deur 011 682 1169 te kontak

335 mm

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MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclude Professional Information & Dimension change.

1. Product: HYLOKAT (Losartan potassium and Hydrochlorothiazide Tablets)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 335 (L) x 280 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM03923602
11. Artwork has been made: Actual Size	12. Pharma code No.: 32984 mini
13. Barcode/NDC No: NA	14. Supersedes Item code No: PM03923601
15. Revision No: 01	16. A/W File name: X:\Losartan HCTZ\SA Private Market\01\HYLOKAT Leaflet PM03923602.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD/MEDICAL	QC	PRODN	QA
30/05/23	Vanita Rajool	31/05/23	05/06/23	6/6/23	21/06/23

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

QA 21/06/23

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa - (Private Market)	PM03923601	20/08/22	11/11/22
2) Exclude Professional Information & Dimension change.	PM03923602		

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