Front Side

420 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

NIOSAR CO 80/12,5 mg Film-coated tablets
NIOSAR CO 160/12,5 mg Film-coated tablets
NIOSAR CO 160/25 mg Film-coated tablets
NIOSAR CO 320/12,5 mg Film-coated tablets
NIOSAR CO 320/25 mg Film-coated tablets
Valsartan and Hydrochlorothiazide
Sugar free

Read all of this leaflet carefully before you start taking NIOSAR CO
- 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.
- **NIOSAR CO** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What NIOSAR CO is and what it is used for

NIOSAR CO film-coated tablets contain two active substances called valsartan and hydrochlorothiazide.
Both of these substances help to control high blood pressure (hypertension).
- Valsartan belongs to a class of medicines known as "angiotensin II receptor antagonists", which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax, and blood pressure is lowered.
- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics (also known as "water tablets"). Hydrochlorothiazide increases urine output, which also lowers blood pressure.
  NIOSAR CO is used to treat high blood pressure, which is not adequately controlled by a single substance alone.

2. What you need to know before you take NIOSAR CO

Do not take NIOSAR CO:
- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide or any of the other ingredients of **NIOSAR CO** (listed in **section 6**).
- if you have developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) – you should never take these medicines again.
- if you suffer from obstruction of blood vessels to your heart or kidneys.
- if you suffer from severe kidney function impairment.
- if you suffer from porphyria.
- if you are currently taking lithium.
- if you are currently taking potassium sparing water tablets containing spironolactone, triamterene or amiloride.
- if you are taking fluoroquinolones (antibiotics to treat infections)
- if you are currently taking aliskiren-containing medicines.
- if you are pregnant or breast-feeding.
- if the level of potassium or sodium in your blood is lower than normal, or if the level of calcium in your blood is higher than normal despite treatment.

NIOSAR CO
(film-coated tablet)
PM04341193

Warnings and precautions

Take special care with NIOSAR CO:
- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- if you have low levels of potassium in your blood.
- if you have diarrhoea or severe vomiting.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you are suffering from heart failure or have experienced a heart attack.

Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.
- if you suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney.
- if you suffer from hyperaldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of **NIOSAR CO** is not recommended.
- if you have liver or kidney disease.
- if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking **NIOSAR CO**, stop taking **NIOSAR CO** immediately and never take it again.

See also **section 4, "Possible side effects"**.
- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or triglycerides in your blood.
- if you have had allergic reactions with the use of other blood pressure-lowering medicines of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- if you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to a week of taking **NIOSAR CO**. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy you can be at higher risk of developing this.
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE inhibitors (for example enalapril, lisinopril, Ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking **NIOSAR CO**.

Contact your doctor to re-evaluate your treatment If you are treated with ACE inhibitors/Angiotensin receptor blockers together with a fluoroquinolone antibiotic. Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

See also information under the heading "**Do not take NIOSAR CO**" **NIOSAR CO** may cause increased sensitivity of the skin to sun.

Children and adolescents
The use of **NIOSAR CO** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and NIOSAR CO
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

The effect of the treatment can be influenced if **NIOSAR CO** is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This especially applies to the following medicines:
- lithium, a medicine used to treat some types of psychiatric diseases.
- medicines or substances that may increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, carbenoxolone, amphotericin or penicillin G.
- some antibiotics (rifamycin group), a medicine used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of **NIOSAR CO**.
- medicines that may induce "torsades de pointes" (irregular heart beat), such as antidysrhythmics (medicines used to treat heart problems) and some antipsychotics.
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics.
- medicines for the treatment of gout, such as allopurinol, probenecid, sulfinpyrazone.
- therapeutic vitamin D and calcium supplements.
- medicines for the treatment of diabetes (oral medicines such as metformin or insulins).
- other medicines to lower your blood pressure including methyldopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the headings "**Do not take NIOSAR CO**" and "**Warnings and precautions**").
- medicines to increase blood pressure, such as noradrenaline or adrenaline.
- digoxin or other digitalis glycosides (medicines used to treat heart problems).
- medicines that may increase blood sugar levels, such as diazoxide or beta blockers.
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide.
- pain killers such as non-steroidal anti-inflammatory medicines (NSAIDs), including selective cyclo-oxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3 g.
- muscle relaxing medicines, such as tubocurarine.
- anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia).
- amantadine (medicine used to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses).
- cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood).
- ciclosporin, a medicine used for organ transplant to avoid organ rejection.
- alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effect used for example during surgery).
- iodine contrast media (agents used for imaging examinations).

NIOSAR CO with food and drink
NIOSAR CO may be taken with or without food. Avoid drinking alcohol as alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

Pregnancy, breast-feeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking **NIOSAR CO**.

Do not take **NIOSAR CO** if you are pregnant, are considering becoming pregnant or are breastfeeding.
If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines
Before you drive a vehicle, use tools or operate machines or carry out other activities that require concentration, make sure you know how **NIOSAR CO** affects you. Like many other medicines used to treat high blood pressure, **NIOSAR CO** may occasionally cause dizziness and affect the ability to concentrate.

3. How to take NIOSAR CO

Do not share medicines prescribed for you with any other person.
Always take **NIOSAR CO** exactly as your doctor has told you. Check with your doctor if you are not sure.
Your doctor will tell you exactly how many tablets of **NIOSAR CO** to take.
Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.
- The recommended dose of **NIOSAR CO** is one tablet per day.
- Do not change the dose or stop taking the tablets without consulting your doctor.
- **NIOSAR CO** should be taken at the same time each day, usually in the morning.
- You can take **NIOSAR CO** with or without food.
- Swallow the tablet with a glass of water.

NIOSAR CO tablets are only for adults and should not be taken by children and adolescents up to 18 years.
If you have the impression that **NIOSAR CO** is too strong or too weak, talk to your doctor or pharmacist.

If you take more NIOSAR CO than you should
If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take NIOSAR CO
If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten dose.

Effects when treatment with NIOSAR CO is stopped:
Stopping your treatment with **NIOSAR CO** may cause your high blood pressure to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

NIOSAR CO can have side effects.
Not all side effects reported for **NIOSAR CO** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **NIOSAR CO**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **NIOSAR CO** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to **NIOSAR CO**. 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:
- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis),
- decrease in vision or pain in your eyes due to high pressure (possible signs of acute angleclosure glaucoma),
- fever, sore throat, more frequent infections (agranulocytosis).

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

Tell your doctor if you notice any of the following:
Frequent
- low level of potassium in the blood,
- increase of lipids in the blood,
- low level of sodium in the blood,
- low level of magnesium in the blood
- high level of uric acid in the blood,
- itchy rash and other types of rash,
- reduced appetite,
- mild nausea and vomiting,
- dizziness, fainting on standing up,
- inability to achieve or maintain erection

Less frequent:
- cough,
- low blood pressure,
- light-headedness,
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark colored urine, dry skin),
- muscle pain,
- tiredness,
- tingling or numbness,
- blurred vision,
- noises (e.g. hissing, buzzing) in ears,
- dizziness,
- diarrhoea,
- joint pain.
- spinning sensation,
- abdominal pain
- swelling and blistering of the skin (due to increased sensitivity to sun),
- high level of calcium in the blood,
- high level of sugar in the blood,
- sugar in the urine,
- worsening of diabetic metabolic state,
- constipation, diarrhoea, discomfort of the stomach or bowels, liver disorders which can occur together with yellow skin and eyes,
- irregular heartbeat,
- headache,
- sleep disturbances,
- sad mood (depression),
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin),
- tingling or numbness,
- vision disorder,
- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis),
- rash, itching, hives, difficulty breathing or swallowing, dizziness (hypersensitivity reactions),
- facial rash, joint pain muscle disorder, fever (lupus erythematosus),
- severe upper stomach pain (pancreatitis),
- difficulty breathing with fever, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary oedema),
- pale skin, tiredness, breathlessness, dark urine (haemolytic anaemia),
- fever, sore throat or mouth ulcers due to infections (leucopenia,)
- confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloraemic alkalosis).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com.

By reporting side effects, you can help provide more information on the safety of **NIOSAR CO'**.

5. How to store NIOSAR CO

Store all medicines OUT OF REACH OF CHILDREN.
Store at or below 25 ℃. (Room temperature) No excursions permitted.
Protect from light and moisture.
Keep the blister in the carton until required for use.
Keep the container closed
Do not use after the expiry date stated on the 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 the pack and other information

What NIOSAR CO contains
- The active substances are Valsartan and Hydrochlorothiazide
- The other ingredients are colloidal silicon dioxide, crospovidone, magnesium stearate and microcrystalline cellulose
- The film coating contains hypromellose, polyethylene glycol 8000, talc, titanium dioxide (C.I. no. 77891), iron oxide red (C.I. no. 77491), iron oxide yellow (C.I. no. , 77492), iron oxide black (C.I. no. 77499)

What NIOSAR CO looks like and contents of the pack
NIOSAR CO 80/12,5 mg
Light orange, oval shaped, biconvex, film coated tablets debossed with "L 16" on one side and plain on other side.
NIOSAR CO 160/12,5 mg
Dark red, oval shaped, biconvex, film coated tablets debossed with "L 17" on one side and plain on other side.
NIOSAR CO 160/25 mg
Brown orange, oval shaped, biconvex, film coated tablets debossed with "L 18" on one side and plain on other side.
NIOSAR CO 320/12,5 mg
Pink, oval shaped, biconvex, film coated tablets debossed with "L 19" on one side and plain on other side.
NIOSAR CO 320/25 mg
Yellow, oval shaped, biconvex, film coated tablets debossed with "L 20" on one side and plain on other side.

Contents of the pack:
1) Blister Pack:
Tablets are packed in Clear triplex film PVC/PE/PVDC 250/25/60 with 60 gsm PVDC as the forming material and 25 µ aluminium foil coated with 6-8 gsm heat seal lacquer as the lidding material, packed in a pre-printed carton.
Pack size include 28's or 30's tablets.

2) HDPE Container Pack:
NIOSAR CO 80/12,5 mg:
Tablets are packed in 40 ml or 60 ml white round HDPE container with 33-400 mm neck finish which are closed with 33 mm child resistant closure with pulp and heat seal liner and packed in outer carton.

NIOSAR CO 160/12,5 mg and 160/25 mg:
Tablets are packed in 75 ml white round HDPE container with 33-400 mm neck finish which are closed with 38 mm child resistant closure with pulp and heat seal liner and packed in outer carton.

NIOSARCO 320/12,5 mg and 320/25 mg:
Tablets are packed in 150 ml white round HDPE container with 33-400 mm neck finish which are closed with 38 mm child resistant closure with pulp and heat seal liner and packed in outer carton.
Pack size include 90 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
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Alberton, South Africa.

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NIOSAR CO 80/12,5 mg: 48/7.1.3/0567
NIOSAR CO 160/12,5 mg: 48/7.1.3/0568
NIOSAR CO 160/25 mg: 48/7.1.3/0569
NIOSAR CO 320/12,5 mg: 48/7.1.3/0570
NIOSAR CO 320/25 mg: 48/7.1.3/0571

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

335 mm

Back Side

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S3

NIOSAR CO 80/12,5 mg Filmbedekte tablette
NIOSAR CO 160/12,5 mg Filmbedekte tablette
NIOSAR CO 160/25 mg Filmbedekte tablette
NIOSAR CO 320/12,5 mg Filmbedekte tablette
NIOSAR CO 320/25 mg Filmbedekte tablette
Valsartan en Hidrochloortiasied
Suikervry

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy NIOSAR CO 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
- **NIOSAR CO** 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 in hierdie inligtingstuk is

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

1. Wat NIOSAR CO is en waarvoor dit gebruik word

NIOSAR CO filmbedekte tablette bevat twee aktiewe bestanddele naamlik valsartan en hidrochloortiasied.
Beide van hierdie bestanddele help om hoë bloeddruk (hipertensie) te beheer.
- Valsartan behoort tot 'n groep van medisyne bekend as angiotensien II reseptor antagoniste, wat help om hoë bloeddruk te beheer. Angiotensien II is 'n stof in die liggaam wat veroorsaak dat bloedvate saamtrek en sodoende veroorsaak dat jou bloeddruk verhoog. Valsartan werk deur die effek van angiotensien II te blokkeer. As 'n resultaat, ontspan bloedvate en word bloeddruk verlaag.
- Hidrochloortiasied behoort tot 'n groep van medisyne bekend as tiasieddiuretika (ook bekend as "water tablette") Hidrochloortiasied verhoog urienuitset wat ook bloeddruk verlaag.

NIOSAR CO word gebruik om hoë bloeddruk te behandel, wat nie voldoende beheer word deur 'n enkele bestanddeel alleen nie.

2. Wat jy behoort te weet voordat jy NIOSAR CO neem

Moet nie NIOSAR CO neem nie
- indien jy allergies (hipersensitief) vir valsartan, hidrochloortiasied of enige van die ander bestanddele van **NIOSAR CO** is nie (gelys in **afdeling 6**).
- indien jy swelling van die gesig, lippe, mond, tong of keel, en reusagtige swelsels op jou vel ontwikkel het terwyl jy voorheen medisyne, naamlik angiotensien omskakelings ensiem (AOE) inhibeerders of angiotensien reseptor blokkeerders (ARB's) geneem het nie – jy moet nooit weer hierdie medisyne gebruik nie.
- indien jy ly aan obstruksie van bloedvate na jou hart of niere.
- indien jy ly aan ernstige inkorting van nierfunksie.
- indien jy ly aan porfirie.
- indien jy tans litium neem.
- indien jy tans kaliumsparende watertablette gebruik wat spironolaktoon, triamtereen of amiloried bevat.
- indien jy fluorokinolone (antibiotika om infeksies te behandel) gebruik.
- indien jy tans aliskiren bevattende medisyne neem.
- indien jy swanger is of borsvoed.
- indien die kalium- of natriumvlak in jou bloed laer as normaal is, of as die kalsiumvlak in jou bloed hoër as normaal is ten spyte van behandeling.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met NIOSAR CO:
- indien jy kaliumsparende medisyne, kaliumaanvullings, sout vervangers wat kalium bevat of ander medisyne neem wat die hoeveelheid kalium in jou bloed verhoog, soos heparien. Jou dokter sal moontlik gereeld die hoeveelheid kalium in jou bloed toets.
- indien jy lae kaliumvlakke in jou bloed het.
- indien jy diaree het of erge braking.
- indien jy hoë dosisse watertablette (diuretika) neem.
- indien jy ernstige hartsiekte het.
- indien jy aan hartversaking ly of 'n hartaanval ervaar het. Volg jou dokter se instruksies noukeurig vir die aanvangsdosis. Jou dokter kan ook moontlik jou nierfunksie nagaan.
- indien jy aan 'n vernouing van die nierslagaar ly.
- indien jy onlangs 'n nuwe nier ontvang het.
- indien jy aan hiperaldosteronisme ly. Dit is 'n siekte waarin jou byniere te veel van die hormoon aldosteroon vervaardig. Indien dit op jou van toepassing is, word die gebruik van **NIOSAR CO** nie aanbeveel nie.
- indien jy 'n lewer- of niersiekte het.
- vertel jou dokter as jy al ooit swelling van die tong en gesig ervaar het wat veroorsaak is deur 'n allergiese reaksie, naamlik angioëdeem, wanneer jy 'n ander middel (insluitend AOE inhibeerders) gebruik. Indien hierdie simptome voorkom wanneer jy **NIOSAR CO** neem, hou dadelik op om **NIOSAR CO** te gebruik en moet dit nooit weer neem nie. Sien ook **afdeling 4 "Moontlike newe-effekte"**.
- indien jy koors, uitslag en gewrigspyn het, wat tekens van sistemiese lupus eritemateuses (SLE, 'n sogenaamde outoïmmuun siekte) kan wees.
- indien jy diabetes, jig, hoë vlakke van cholesterol of trigliseriede in jou bloed het.
- indien jy allergiese reaksies gehad het met die gebruik van ander bloeddruk-verlagende medisyne van hierdie klas (angiotensien II reseptor antagoniste) of as jy allergie of asthma het.
- indien jy 'n afname in sig of oogpyn ervaar. Dit kan simptome wees van 'n toename in druk in jou oog en kan binne ure tot 'n week gebeur na die neem van **NIOSAR CO**. Indien dit nie behandel word nie kan dit lei tot permanente sigverlies. Jy kan 'n hoër risiko geval wees om hierdie te ontwikkel, indien jy vroeër 'n penisillien- of sulfoonamied allergie gehad het.
- indien jy enige van die volgende medisyne neem, wat gebruik word om hoë bloeddruk te behandel:
  - 'n AOE inhibeerder (byvoorbeeld enalapril, lisinopril, ramipril), veral as jy diabetes verwante nierprobleme het.
  - aliskiren.
- indien jy velkanker het of jy 'n onverwagte velletsel ontwikkel gedurende die behandeling.

Behandeling met hidrochloortiasied, veral langtermyn gebruik met hoë dosisse, kan die risiko van sommige tipes vel- en lipkanker (nie-melanoom velkanker) verhoog. Beskerm jou vel teen sonblootstelling en UV-strale terwyl jy **NIOSAR CO** gebruik.
Kontak jou dokter om jou behandeling te herevalueer, indien jy met AOE inhibeerders/Angiotensien reseptor blokkeerders behandel word, saam met 'n fluorokinoloon antibiotikum.
Jou dokter kan jou nierfunksie, bloeddruk en die hoeveelheid elektroliete (bv. kalium) in jou bloed met gereelde tussenposes nagaan.
Sien ook inligting onder die opskrif "**Moet nie NIOSAR CO neem nie**".
NIOSAR CO kan verhoogde sensitiwiteit van die vel, vir son veroorsaak.

Kinders en adolessente
Die gebruik van **NIOSAR CO** in kinders en adolessente (jonger as 18 jaar) word nie aanbeveel nie.

Ander medisyne en NIOSAR CO
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).
Die uitwerking van die behandeling kan beïnvloed word wanneer **NIOSAR CO** saam met sekere ander medisyne geneem word. Dit mag nodig wees om die dosis te verander, om ander voorsorgmaatreëls te tref, of, in sommige gevalle om op te hou om een van die medisyne te neem. Hierdie is veral van toepassing op die volgende medisyne:
- litium, 'n medisyne wat gebruik word om sommige soorte psigiatriese siektes te behandel.
- medisyne of middels wat die hoeveelheid kalium in jou bloed verhoog. Dit sluit kaliumaanvullings of soutvervangers wat kalium bevat, kaliumsparende medisyne en heparien in.
- medisyne wat die hoeveelheid kalium in jou bloed kan verminder, soos diuretika (water tablette), kortikosteroïede, lakseermiddels, karbenoksoloon, amfoterisien of penisillien G.
- sommige antibiotika (rifamisien groep), 'n medisyne wat gebruik om teen orgaanverwerping te beskerm (siklosporien) of 'n anti-retrovirale medisyne wat gebruik word om MIV/VIGS infeksie te behandel (ritonavir). Hierdie medisyne kan die effek van **NIOSAR CO** verhoog.
- medisyne wat "*torsades de pointes*" (onreëlmatige hartklop) kan veroorsaak, soos anti-disritmiese middels (medisyne wat gebruik word om hartprobleme te behandel) en sommige anti-psigotiese middels.
- medisyne wat die hoeveelheid natrium in jou bloed kan verminder, soos antidepressante, anti-psigotiese middels, anti-epileptikum.
- medisyne vir die behandeling van jig, soos allopurinol, probenesied, sulfinpirasoon.
- terapeutiese vitamien D en kalsiumaanvullings.
- medisyne vir die behandeling van diabetes (orale medisyne soos metformien of insulien).
- ander medisyne om jou bloeddruk te verlaag, insluitend metieldopa, AOE inhibeerders (soos enalapril, lisinopril, ens.) of aliskiren (sien ook inligting onder die opskrifte "**Moet nie NIOSAR CO neem nie**" en "**Waarskuwings en voorsorgmaatreëls**").
- medisyne om bloeddruk te verhoog, soos noradrenalien of adrenalien.
- digoksien of ander digitalis-glikosiede (medisyne wat gebruik word om hartprobleme te behandel).
- medisyne wat bloedsuikervlakke kan verhoog, soos diasoksied of beta-blokkeerders.
- sitotoksiese middels (wat gebruik word om kanker te behandel), soos metotreksaat of siklofosfamied.
- pynstillers soos nie-steroïed anti-inflammatoriese medisyne (NSAIM's), insluitend selektiewe siklo-oksigenase-2 inhibeerders (COX-2 inhibeerders) en asetielsalisielsuur > 3 g.
- spierverslappende medisyne, soos tubokurarien.
- anti-cholinergiese middels (medisyne wat gebruik word om 'n verskeidenheid van afwykings te behandel, soos gastroïntestinale krampe, urinêre blaasspasma, asma, bewegingsiekte, spierspasmas, Parkinson se siekte en as 'n hulpmiddel vir narkose).
- amantadien (medisyne wat gebruik word om Parkinson se siekte te behandel en ook gebruik word om sekere siektes wat deur virusse veroorsaak word, te behandel of te voorkom).
- cholestiramien en kolestipol (medisyne wat hoofsaaklik gebruik word om hoë vlakke van lipiede in die bloed te behandel).
- siklosporien, 'n medisyne wat gebruik word vir orgaanoorplanting om orgaanverwerping te verhoed.
- alkohol, slaappille en anestetikum (medisyne met slaap- of pynstillende effek wat byvoorbeeld tydens chirurgie gebruik word).
- jodiumkontrasmedia (middels wat gebruik word vir beeldondersoeke).

NIOSAR CO met voedsel en drank
NIOSAR CO tablette kan met, of sonder voedsel geneem word. Vermy die drink van alkohol aangesien alkohol kan meebring dat jou bloeddruk verder daal en/of die risiko kan verhoog dat jy duiselig of flou word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, vermoed dat jy moontlik swanger kan wees of beplan om 'n baba te hê, vra jou dokter of apteker vir advies voordat jy **NIOSAR CO** neem.

Moet nie **NIOSAR CO** neem as jy swanger is, oorweeg om swanger te raak, of borsvoed nie.
Indien jy 'n vrou van kinderbarende ouderdom is, moet jy effektiewe voorbehoeding gebruik.

Bestuur en gebruik van masjinerie
Voordat jy 'n voertuig bestuur, gereedskap gebruik of masjienerie bedryf, of ander aktiwiteite uitvoer wat konsentrasie verg, moet jy seker maak dat jy weet hoe **NIOSAR CO** jou affekteer. Soos baie ander medisyne wat gebruik word om hoë bloeddruk te behandel, kan **NIOSAR CO** af en toe duiseligheid veroorsaak en die vermoë om te konsentreer, beïnvloed**.**

3. Hoe om NIOSAR CO te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **NIOSAR CO** presies soos jou dokter vir jou gesê het. Bevestig met jou dokter indien jy nie seker is nie.
Jou dokter sal vir jou sê presies hoeveel **NIOSAR CO** tablette om te neem.
Afhangende van hoe jy op die behandeling reageer, kan jou dokter 'n hoër of laer dosis aanbeveel.
- Die aanbevole dosis vir **NIOSAR CO** is een tablet per dag.
- Moet nie die dosis verander of ophou om die tablette te neem sonder om jou dokter te raadpleeg nie.
- **NIOSAR CO** moet elke dag op dieselfde tyd geneem word, gewoonlik in die oggend.
- Jy kan **NIOSAR CO** met of sonder kos neem.
- Sluk die tablet met 'n glas water

NIOSAR CO tablette is slegs vir volwassenes en moet nie deur kinders en adolessente tot op 18 jaar geneem word nie.

Indien jy onder die indruk is dat **NIOSAR CO** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer NIOSAR CO geneem het as wat jy behoort te neem
Indien jy erge duiseligheid en/of floute ervaar, kontak jou dokter onmiddellik, en gaan lê. In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om NIOSAR CO te neem
Indien jy vergeet om 'n dosis te neem, neem dit sodra jy onthou. Indien dit egter amper tyd is vir jou volgende dosis, slaan die dosering oor wat jy gemis het. Moet nie 'n dubbele dosis neem om vir 'n vergete dosering op te maak nie

Effekte wanneer behandeling met NIOSAR CO gestaak word
Om jou behandeling met **NIOSAR CO** te staak, kan veroorsaak dat jou hoë bloeddruk vererger. Moet nie ophou om jou medisyne te neem nie, tensy jou dokter vir jou sê om dit te doen.

4. Moontlike newe-effekte

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

Indien enige van die volgende gebeur, hou op om **NIOSAR CO** te gebruik en vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal,
- uitslag of jeuk.

Al hierdie newe-effekte is baie ernstig. Indien jy dit ervaar, het jy moontlik 'n ernstige reaksie op **NIOSAR CO** gehad. Jy mag dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- ernstige velsiekte wat uitslag, rooi vel, blase op die lippe, oë of mond veroorsaak, afskilfering van vel, koors (toksiese epidermale nekrolise),
- afname in sig of pyn in jou oë as gevolg van hoë druk (moontlike tekens van akute toehoek gloukoom),
- koors, seer keel, meer gereelde infeksies (agranulositose).

Al hierdie newe-effekte is ernstig. Jy mag moontlik dringende mediese aandag benodig.

Vertel vir jou dokter indien jy enige van die volgende opmerk:
Gereeld:
- lae kaliumvlakke in die bloed,
- toename in lipiede in die bloed,
- lae natriumvlakke in die bloed,
- lae magnesiumvlakke in die bloed,
- hoë uriensuurvlakke in die bloed,
- jeukerige uitslag en ander soorte uitslag,
- verminderde eetlus,
- ligte naarheid en braking,
- duiseligheid, floute wanneer jy opstaan,
- onvermoë om ereksie te bereik of te handhaaf.

Minder gereeld:
- hoes,
- lae bloeddruk,
- lighoofdigheid,
- dehidrasie (met simptome van dors, droë mond en tong, ongereelde urinering, donkerkleurige uriene, droë vel),
- spierpyn,
- moegheid,
- tinteling of gevoelloosheid,
- dowwe visie,
- geraas (bv. suising, gonsing) in ore,
- duiseligheid,
- diaree,
- gewrigspyn,
- draai sensasie,
- abdominale pyn,
- swelling van, en blase op die vel (as gevolg van verhoogde sensitiwiteit vir son),
- hoë kalsiumvlak in die bloed,
- hoë suikervlak in die bloed,
- suiker in die uriene,
- verergering van diabetiese metaboliese toestand,
- hardlywigheid, diaree, ongemak van die maag of ingewande, lewerafwykings wat saam met geel vel en oë kan voorkom,
- onreëlmatige hartklop,
- hoofpyn,
- slaapversteurings,
- hartseer bui (depressie),
- lae vlak van bloedplaatjies (soms met bloeding of kneusing onder die vel),
- tinteling of gevoelloosheid,
- sigversteuring,
- inflammasie van bloedvate met simptome soos uitslag, persrooi kolle, koors (vaskulitis),
- uitslag, jeuk, galbulte, moeilike asemhaling of sluk, duiseligheid (hipersensitiwiteitsreaksies),
- veluitslag in die gesig, gewrigspyn spierafwyking, koors (lupus eritemateuses),
- erge boonste maagpyn (pankreatitis),
- moeilike asemhaling met koors, asemgefluit, uitasem (respiratoriese nood insluitend longontsteking en pulmonêre edeem),
- bleek vel, moegheid, uitasem, donker uriene (hemolitiese anemie),
- koors, seer keel of mondsere as gevolg van infeksies (leukopenie),
- verwarring, moegheid, spiertrekkings en -spasma, vinnige asemhaling (hipochloremiese alkalose).

Lig asseblief jou dokter of apteker in indien jy enige newe-effekte ervaar 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 gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com.

Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **NIOSAR CO.**

5. Hoe om NIOSAR CO te bewaar

Bewaar alle medisyne BUITE BEREIK VAN KINDERS.
Bewaar by of benede 25 °C. (Kamertemperatuur). Geen afwyking word toegelaat nie.
Beskerm teen vog en lig.
Hou die stulpstrook in die buitenste karton totdat dit benodig word vir gebruik.
Hou die houer dig toe.
Moet nie na die vervaldatum, wat aangebring is op die etiket/karton/bottel, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat NIOSAR CO bevat
- Die aktiewe bestanddele is valsartan en hidrochloortiasied.
- Die ander bestanddele is kolloïdale silikondioksied, krospovidoon, magnesiumstearaat en mikrokristallyne sellulose.
- Die filmbedekking bevat hipromellose, poliëtileenglikol 8 000, talk, titaniumdioksied (C.I. nr. 77891) rooi ysteroksied (C.I. nr. 77491), geel ysteroksied (C.I. nr. 77492), swart ysteroksiek (C.I. nr. 77499).

Hoe NIOSAR CO lyk en inhoud van die pak
NIOSAR CO 80/12,5
Lig oranje, ovaalvormige, bikonvekse, filmbedekte tablette met "L16" op een kant gedruk en glad aan die ander kant.

NIOSAR CO 160/12,5
Donkerrooi, ovaalvormige, bikonvekse, filmbedekte tablette met "L17" op een kant gedruk en glad aan die ander kant.

NIOSAR CO 160/25
Bruin oranje, ovaalvormige, bikonvekse, filmbedekte tablette met "L18" op een kant gedruk en glad aan die ander kant.

NIOSAR CO 320/12,5
Pienk, ovaalvormige, bikonvekse, filmbedekte tablette met "L19" op een kant gedruk en glad aan die ander kant.

NIOSAR CO 320/25
Geel, ovaalvormige, bikonvekse, filmbedekte tablette met "L20" op een kant gedruk en glad aan die ander kant.

Inhoud van die pak:
1) Stulpverpakking:
Tablette word verpak in deursigtige tripleks film PVC/PE/PVDC 250/25/60 met 60 gsm PVDC as die vormingsmateriaal en 25 µ aluminiumfoelie bedek met 6-8 gsm hitteseëllak as dekmateriaal, verpak in 'n voorafgedrukte karton.
Verkpakkingsgrootte sluit 28's of 30's tablette in.

2) HDPE houer verpakking:
NIOSAR CO 80/12,5 mg:
Tablette word verpak in 40 ml of 60 ml wit ronde HDPE houer met 33-400 mm nek afwerking wat gesluit is met 33 mm kinderbestande sluiting met pulp en hitteseëlvoering en verpak in buitenste karton.

NIOSAR CO 160/12,5 mg en 160/25 mg:
Tablette word verpak in 75 ml wit ronde HDPE houer met 33-400 mm nek afwerking wat gesluit is met 38 mm kinderbestande sluiting met pulp en hitteseëlvoering en verpak in buitenste karton.

NIOSARCO 320/12,5 mg en 320/25 mg:
Tablette word verpak in 150 ml wit ronde HDPE houer met 33-400 mm nek afwerking wat gesluit is met 38 mm kinderbestande sluiting met pulp en hitteseëlvoering en verpak in buitenste karton.
Verkpakkingsgroottes sluit 90 tablette in.
Nie alle verpakkings en verpakkingsgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
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
28 Februarie 2022

Registrasienommers
NIOSAR CO 80/12,5 mg: 48/7.1.3/0567
NIOSAR CO 160/12,5 mg: 48/7.1.3/0568
NIOSAR CO 160/25 mg: 48/7.1.3/0569
NIOSAR CO 320/12,5 mg: 48/7.1.3/0570
NIOSAR CO 320/25 mg: 48/7.1.3/0571

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@macleodspharma. com of kontak 011 682 1169

420 mm

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Professional information removed, website added & dimension change.

1. Product: NIOSAR CO (Valsartan HCTZ 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: 420 (L) x 335 (W) mm**
9. Design / Style: NA	**10. Item code No.: PM04341193**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40812 mini**
13. Barcode/NDC No: NA	**14. Supersedes Item code No: NA**
15. Revision No: 01	**16. A/W File name: E:\SOUTH AFRICA\South Africa\Valsartan HCTZ\Private Market\01\Valsartan HCTZ PIL - PM04341193.cdr**
Approved By:	**17. Location: Daman / Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	07/01/2026				

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.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa (Private Market)	PM04083101	14/02/23	11/08/2023
2) Professional information removed, website added & dimension change.	PM04341193		