420 mm

NEOTECLA 30 mg
NEOTECLA 60 mg
NEOTECLA 90 mg
PM04313002

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

NEOTECLA 30 mg (film coated tablet)
NEOTECLA 60 mg (film coated tablet)
NEOTECLA 90 mg (film coated tablet)
Cinacalcet hydrochloride
Contains sugar – lactose monohydrate
NEOTECLA 30 mg: contains 76,707 mg lactose monohydrate.
NEOTECLA 60 mg: contains 153,42 mg lactose monohydrate.
NEOTECLA 90 mg: contains 230,13 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking NEOTECLA
- 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.
- **NEOTECLA** 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 **NEOTECLA** is and what it is used for
2. What you need to know before you take **NEOTECLA**
3. How to take **NEOTECLA**
4. Possible side effects
5. ow to store **NEOTECLA**
6. Contents of the pack and other information

1. What NEOTECLA is and what it is used for

NEOTECLA contains Cinacalcet hydrochloride.

NEOTECLA works by controlling the levels of parathyroid hormone (PTH), calcium and phosphorous in your body. It is used to treat problems with organs called parathyroid glands. The parathyroid are four small glands in the neck, near the thyroid gland, that produce parathyroid hormone (PTH).

NEOTECLA is used in adults:
- to treat secondary hyperparathyroidism in adults with serious kidney disease who need dialysis to clear their blood of waste products.
- to reduce high levels of calcium in the blood (hypercalcaemia) in adult patients with parathyroid cancer.

2. What you need to know before you take NEOTECLA

Do not take NEOTECLA:
- If you are allergic to Cinacalcet or any of the other ingredients of this medicine, listed in section 6.
- If you have low levels of calcium in your blood. Your doctor will monitor your blood calcium levels.

Warnings and precautions
Talk to your doctor before taking **NEOTECLA**
Before you start taking **NEOTECLA**, tell your doctor if you have or have ever had:
- Seizures (fits or convulsions). The risk of having seizures is higher if you have had them before
- Liver problems
- heart failure and low blood pressure.

NEOTECLA reduces calcium levels. Life threatening events and fatal outcomes associated with low calcium levels (hypocalcaemia) have been reported in adults treated with **NEOTECLA**.
Please tell your doctor if you experience any of the following which may be signs of low calcium levels: spasms, twitches, or cramps in your muscles, or numbness or tingling in your fingers, toes or around your mouth or seizures, confusion or loss of consciousness while being treated with **NEOTECLA**.
Low calcium levels can have an effect on your heart rhythm. Tell your doctor if you experience an unusually fast or pounding heartbeat, if you have heart rhythm problems, or if you take medicines known to cause heart rhythm problems, while taking **NEOTECLA**.
For additional information see section 4.

If you have kidney failure and are not on dialysis, you should not take **NEOTECLA**.
If you have low blood pressure or worsening heart failure.
If you have bone disease, your doctor may reduce your dose or discontinue therapy.
NEOTECLA contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

During treatment with **NEOTECLA**, tell your doctor if you start or stop smoking, as this may affect the way **NEOTECLA** works.
If you are being treated for secondary hyperparathyroidism, your doctor should monitor your calcium levels before starting treatment with **NEOTECLA** and during treatment with **NEOTECLA**. You should inform your doctor if you experience any of the signs of low calcium levels as described above.
If you are being treated with etelcalcetide (used to treat secondary hypoparathyroidism, you should not use **NEOTECLA**.

Use in children and adolescents
The use of **NEOTECLA** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and NEOTECLA
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 taking any of the following medicines:
- if you are taking, have recently taken or might take any other medicines particularly etelcalcetide or any other medicines that lower the level of calcium in your blood.
- You should not receive **NEOTECLA** together with etelcalcetide.
- medicines used to treat skin and fungal infections (ketoconazole, itraconazole and voriconazole);
- medicines used to treat bacterial infections (telithromycin, rifampicin and ciprofloxacin);
- a medicine used to treat HIV infection and AIDS (ritonavir)
- a medicine used to treat depression (fluvoxamine).
- medicines used to treat depression (amitriptyline, desipramine, nortriptyline and clomipramine);
- a medicine used to relieve cough (dextromethorphan);
- medicines used to treat changes in heart rate (flecainide and propafenone);
- a medicine used to treat high blood pressure (metoprolol).

NEOTECLA with food and drink:
NEOTECLA should be taken with or shortly after food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **NEOTECLA**.

Safety in pregnancy and during breastfeeding has not been established.

Driving and using machines
Dizziness and seizures have been reported by patients taking **NEOTECLA**. If you experience these side effects, do not drive or operate machines.
It is not always possible to predict to what extent **NEOTECLA** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **NEOTECLA** affects them.

3. How to take NEOTECLA

Do not share medicines prescribed for you with any other person.

Always take **NEOTECLA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

If you are being treated for secondary hyperparathyroidism
The usual starting dose for **NEOTECLA** in adults is 30 mg (one tablet) once per day.
If you are being treated for parathyroid cancer or primary hyperparathyroidism
The usual starting dose for **NEOTECLA** in adults is 30 mg (one tablet) twice per day.
NEOTECLA must be taken orally, with or shortly after food. Tablets should be taken whole and not divided.

If you have the impression that the effect of **NEOTECLA** is too strong or too weak, talk to your doctor or pharmacist.

If you take more NEOTECLA 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.

If you forget to take NEOTECLA
It is important to take your **NEOTECLA** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking NEOTECLA
If **NEOTECLA** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **NEOTECLA** for as long as your doctor has prescribed.

4. Possible side effects

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

If any of the following happens, stop taking **NEOTECLA** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- If you start to get numbness or tingling around the mouth, muscle aches or cramps and seizures. These may be signs that your calcium levels are too low (hypocalcaemia).
- If you experience swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema).

These are all very serious side effects. If you have them, you may have had a serious reaction to **NEOTECLA**. You may need urgent medical attention or hospitalisation.
Tell your doctor if you notice any of the following:
Frequently occurring:
- Nausea and vomiting, these are usually mild and do not last for long.
- Dizziness
- Numbness or tingling sensation (paraesthesia)
- Loss (anorexia) or decrease in appetite
- Muscle pain (myalgia)
- Weakness (asthenia)
- Rash
- Reduced testosterone levels
- High potassium levels in the blood (hyperkalaemia)
- Allergic reactions (hypersensitivity)
- Headache
- Seizures
- Low blood pressure (hypotension)
- Upper respiratory tract infection
- Breathing difficulties (dyspnoea)
- Cough
- Indigestion (dyspepsia)
- Diarrhoea
- Abdominal pain, abdominal pain – upper
- Constipation
- Muscle spasms
- Back pain
- Low calcium levels in the blood (hypercalcaemia)

Frequency unknown
- Unusually fast or pounding heart beat which may be associated with low levels of calcium in your blood (QT prolongation and ventricular arrhythmia secondary to hypocalcaemia).
- After taking NEOTECLA a very small number of patients with heart failure had worsening of their condition and/or low blood pressure (hypotension).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Should your general health worsen or if you experience any untoward effects while taking **NEOTECLA**, please consult your healthcare provider for advice.

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 **NEOTECLA**.

5. How to store NEOTECLA

Store at or below 30 °C.
KEEP OUT OF THE 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 NEOTECLA contains
The active ingredient is cinacalcet hydrochloride.
Contains sugar – lactose monohydrate
The other ingredients are:
Lactose monohydrate
Microcrystalline cellulose
Crospovidone
Colloidal silicon dioxide
Magnesium stearate
Instacoat Universal green which contains:
- Hypromellose
- Lactose monohydrate
- Triacetin
- Titanium dioxide
- Yellow iron oxide
- FD and C Blue No. 2 Al lake

What NEOTECLA looks like and contents of the pack
NEOTECLA 30 mg: Light green, oval, biconvex, film-coated tablets debossed with 'L83' on one side and plain on other side.
NEOTECLA 60 mg: Light green, oval, biconvex, film-coated tablets debossed with 'L84' on one side and plain on other side.
NEOTECLA 90 mg: Light green, oval, biconvex, film-coated tablets debossed with 'L85' on one side and plain on other side.
Contents of the pack:
Tablets are packed in aluminium foil laminated on one side and laminated to clear PVC on the other side. Pack sizes include 14 or 28 or 30 or 84 tablets.
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Block 1,
Bassonia Estate Office Park (East),
1 Cussonia Drive,
Bassonia Rock Ext 12
Alberton
Gauteng

This leaflet was last revised in
20/03/2024

Registration numbers
NEOTECLA 30 mg: 56/21.12/0707
NEOTECLA 60 mg: 56/21.12/0708
NEOTECLA 90 mg: 56/21.12/0709

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

235 mm

420 mm

235 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

NEOTECLA 30 mg (filmbedekte tablet)
NEOTECLA 60 mg (filmbedekte tablet)
NEOTECLA 90 mg (filmbedekte tablet)
Sinakalkethidrochloried
Bevat suiker – laktosemonohidraat
NEOTECLA 30 mg: bevat 76,707 mg laktosemonohidraat
NEOTECLA 60 mg: bevat 153,42 mg laktosemonohidraat
NEOTECLA 90 mg: bevat 230,13 mg laktosemonohidraat.

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy NEOTECLA 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
- **NEOTECLA** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat NEOTECLA is en waarvoor dit gebruik word

NEOTECLA bevat Sinakalkethidrochloried

NEOTECLA werk deur die vlakke van paratiroïedhormoon (PTH), kalsium en fosfor in jou liggaam te beheer. Dit word gebruik om probleme met organe genaamd paratiroïedkliere, te behandel. Die paratiroïed is vier klein kliere in die nek, naby die tiroïedklier, wat paratiroïedhormoon (PTH) produseer.

NEOTECLA word in volwassenes gebruik:
- om sekondêre hiperparatiroïedisme te behandel in volwassenes met ernstige niersiekte wat dialise benodig om hul bloed van afvalprodukte skoon te maak.
- om hoë kalsiumvlakke in die bloed te verminder (hiperkalsemie) in volwasse pasiënte met paratiroïedkanker.

2. Wat jy behoort te weet voordat jy NEOTECLA neem

Moet nie NEOTECLA neem nie:
- Indien jy allergies is vir Sinakalket of enige van die ander bestanddele van hierdie medisyne, soos gelys in afdeling 6.
- Indien jy lae vlakke van kalsium in jou bloed het. Jou dokter sal jou kalsiumvlakke in jou bloed monitor.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat **NEOTECLA** geneem word
Voordat jy **NEOTECLA** begin gebruik, vertel jou dokter of jy tans het of al ooit gehad het:
- Aanvalle (stuiptrekkings of kovulsies). Die risiko om aanvalle te kry, is groter indien jy dit al voorheen gehad het.
- Lewerprobleme
- hartversaking en lae bloeddruk.

NEOTECLA verlaag kalsiumvlakke. Lewensbedreigende gebeure en noodlottige uitkomste wat verband hou met lae kalsiumvlakke (hipokalsemie) is aangemeld in volwassenes wat met **NEOTECLA** behandel is.
Vertel asseblief jou dokter indien jy enige van die volgende ervaar wat moontlik tekens van lae kalsiumvlakke kan wees: spasmas, senutrekkings, of krampe in jou spiere, of gevoelloosheid of tinteling in jou vingers, tone of om jou mond of aanvalle, verwarring of verlies van bewussyn terwyl jy met **NEOTECLA** behandel word.
Lae kalsiumvlakke kan 'n uitwerking op jou hartritme hê. Vertel jou dokter as jy 'n ongewoon vinnige of bonsende hartklop ervaar, as jy hartritmeprobleme het, of as jy medisyne wat geken word om hartritmeprobleme te veroorsaak neem, terwyl **NEOTECLA** geneem word.
Vir meer inligting sien afdeling 4.

Indien jy nierversaking het en nie op dialise is nie, moet jy nie **NEOTECLA** neem nie.
Indien jy lae bloeddruk of verergerende hartversaking het.
Indien jy beensiekte het, kan jou dokter jou dosis verminder of die behandeling staak.
NEOTECLA bevat laktose
As jy deur jou dokter meegedeel is dat jy 'n intoleransie vir sekere suikers het, kontak jou dokter voordat jy hierdie medisyne neem.

Tydens behandeling met **NEOTECLA**, vertel jou dokter as jy begin of ophou rook, aangesien dit die manier waarop **NEOTECLA** werk kan affekteer.
Indien jy behandel word vir sekondêre hiperparatiroïedisme, moet jou dokter jou kalsiumvlakke monitor voor aanvang van behandeling met **NEOTECLA** en tydens behandeling met **NEOTECLA.** Jy moet jou dokter in kennis stel as jy enige van die tekens van lae kalsiumvlakke ervaar, soos hierbo beskryf.
Indien jy met etelkalsetied behandel word (gebruik om sekondêre hipoparatiroïedisme te behandel), behoort jy nie **NEOTECLA** te gebruik nie.

Gebruik in kinders en adolessente
Die gebruik van **NEOTECLA** in kinders en adolessente (onder die ouderdom van 18 jaar) word nie aanbeveel nie.

Ander medisyne en NEOTECLA
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker as jy enige van die volgende medisyne gebruik:
- indien jy enige ander medisyne neem, onlangs geneem het of moontlik kan neem, veral etelkasetied of enige ander medisyne wat die vlak van kalsium in jou bloed verlaag.
- Jy moet nie **NEOTECLA** saam met etelkasetied ontvang nie.
- medisyne wat gebruik word om vel- en swaminfeksies te behandel (ketokonasool, itrakonasool en vorikonasool);
- medisyne wat gebruik word om bakteriële infeksies te behandel (telitromisien, rifampisien en siprofloksasien);
- 'n medisyne wat gebruik word om MIV-infeksie en vigs te behandel (ritonavir)
- 'n medisyne wat gebruik word om depressie (fluvoksamien) te behandel.
- medisyne wat gebruik word om depressie te behandel (amitriptilien, desipramien, nortriptilien en klomipramien);
- 'n medisyne wat gebruik word om hoes te verlig (dekstrometorfaan);
- medisyne wat gebruik word om veranderinge in hartklop (flekainied en propafenoon) te behandel;
- 'n medisyne wat gebruik word om hoë bloeddruk (metoprolol) te behandel.

NEOTECLA met voedsel en drank
NEOTECLA moet met of kort na kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **NEOTECLA** neem.
Veiligheid in swangerskap en tydens borsvoeding is nie vasgestel nie.

Bestuur en gebruik van masjinerie
Duiseligheid en aanvalle is aangemeld deur pasiënte wat **NEOTECLA** neem. As jy hierdie newe-effekte ervaar, moet jy nie bestuur of masjiene bedryf nie.
Dit is nie altyd moontlik om te voorspel tot watter mate **NEOTECLA** met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waarin **NEOTECLA** hulle affekteer nie.

3. Hoe om NEOTECLA te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie

Neem altyd **NEOTECLA** presies soos jou dokter vir jou gesê het. Jy moet met jou dokter of apteker bevestig indien jy onseker is.

As jy behandel word vir sekondêre hiperparatiroïedisme
Die gewone aanvangsdosis vir **NEOTECLA** in volwassenes is 30 mg (een tablet) een keer per dag.
As jy behandel word vir paratiroïedkanker of primêre hiperparatiroïedisme
Die gewone aanvangsdosis vir **NEOTECLA** in volwassenes is 30 mg (een tablet) twee keer per dag.
NEOTECLA moet oraal ingeneem word, met of kort na kos. Tablette moet heel geneem word en nie verdeel word nie.

Indien jy onder die indruk is dat die effek van **NEOTECLA** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer NEOTECLA 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.

Indien jy vergeet om NEOTECLA te neem
Dit is belangrik om jou **NEOTECLA** gereeld op dieselfde tyd elke dag te neem. As jy vergeet om 'n dosering te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse neem op dieselfde tyd, om op te maak vir 'n oorgeslane dosis nie.

Indien jy ophou om NEOTECLA te gebruik
As **NEOTECLA** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem **NEOTECLA** altyd vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

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

Indien enige van die volgende gebeur, hou op om **NEOTECLA** te neem en sê onmiddelik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- As jy gevoelloosheid of tinteling om die mond begin kry, spierpyne of krampe en aanvalle. Hierdie kan tekens wees dat jou kalsiumvlakke te laag is (hipokalsemie).
- As jy swelling van die gesig, lippe, mond, tong of keel ervaar wat probleme kan veroorsaak met sluk of asemhaling (angioedeem).

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige reaksie teen **NEOTECLA** gehad het. Jy mag dringende mediese aandag of hospitalisering nodig hê.
Sê vir jou dokter indien jy enige van die volgende waarneem:
Kom gereeld voor:
- Naarheid en braking, dit is gewoonlik matig en hou nie vir lank aan nie.
- Duiseligheid
- Gevoelloosheid of tintelende sensasie (parestesie)
- Verlies (anoreksie) of afname in eetlus
- Spierpyn (mialgie)
- Swakheid (astenie)
- Uitslag
- Verlaagde testosteroonvlakke
- Hoë kaliumvlakke in die bloed (hiperkalemie)
- Allergiese reaksies (hipersensitiwiteit)
- Hoofpyn
- Aanvalle
- Lae bloeddruk (hipotensie)
- Infeksie in die boonste lugweë
- Asemhalingsprobleme (dispnee)
- Hoes
- Slegte spysvertering (dispepsie)
- Diarree
- Abdominale pyn, abdominale pyn – boonste
- Hardlywigheid
- Spierspasmas
- Rugpyn
- Lae kalsiumvlakke in die bloed (hiperkalsemie)

Frekwensie onbekend
- Ongewoon vinnige of bonsende hartklop wat moontlik geassosieer kan word met lae vlakke van kalsium in jou bloed (QT verlenging en ventrikulêre aritmie sekondêr tot hipokalsemie).
- Nadat **NEOTECLA** geneem is, het 'n baie klein aantal pasiënte met hartversaking se toestand vererger en/of lae bloeddruk (hipotensie) gekry.

Lig asseblief jou dokter of apteker in indien jy enige newe-effekte ervaar wat nie in hierdie inligtingstuk genoem word nie. Sou jou algemene gesondheid verswak of as jy enige ongewenste effekte ervaar terwyl jy **NEOTECLA** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

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 inligstuk gelys 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 beskikbaar te stel aangaande die veiligheid van **NEOTECLA.**

5. Hoe om NEOTECLA te bewaar

Bewaar by of benede 30°C.
HOU BUITE DIE BEREIK VAN KINDERS
Stoor in die oorspronklike verpakking / houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in die badkamer stoor 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 afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat NEOTECLA bevat
Die aktiewe bestanddeel is sinakalkethidrochloried.
Bevat suiker - laktosemonohidraat
Die ander bestanddele is:
Laktosemonohidraat
Mikrokristallyne sellulose
Krospovidoon
Kolloïdale silikondioksied
Magnesiumstearaat
Instabedekking Universele groen wat bevat:
- Hipromellose
- Laktosemonohidraat
- Triasetien
- Titaandioksied
- Geel ysteroksied
- FD en C Blou No. 2 Al meer

Hoe NEOTECLA lyk en inhoud van die pak
NEOTECLA 30 mg: Liggroen, ovaal, bikonveks, filmbedekte tablette bedruk met 'L83' aan die een kant en glad aan die ander kant.
NEOTECLA 60 mg: Liggroen, ovaal, bikonveks, filmbedekte tablette bedruk met 'L84' aan die een kant en glad aan die ander kant.
NEOTECLA 90 mg: Liggroen, ovaal, bikonveks, filmbedekte tablette bedruk met 'L85' aan die een kant en glad aan die ander kant.

Inhoud van die pak:
Tablette word verpak in aluminiumfoelie wat aan die een kant gelamineer is en gelamineer is tot deursigte PVC aan die ander kant.
Pakgroottes sluit 14 of 28 of 30 of 84 tablette in.
Nie alle pakgroottes word noodwendig bemark nie.

7. Houer van die Registrasiesertifikaat

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Kantoorblok 1,
Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1,
Bassonia Rock, Uitbr. 12,
Alberton
Gauteng

Hierdie inligtingstuk was hersien in
20/03/2024

Registrasienommer
NEOTECLA 30 mg: 56/21.12/0707
NEOTECLA 60 mg: 56/21.12/0708
NEOTECLA 90 mg: 56/21.12/0709

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

MASTER COPY

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Leaflet last revision date is mentioned.

1. Product: NEOTECLA 30/60/90 (Cinacalcet Tablets 30/60/90 mg)	
2. Country: South Africa (Tender)	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 235 (W) mm
9. Design / Style: Booklet type	10. Item code No.: PM04313002
11. Artwork has been made: Actual Size	12. Pharma code No.: 33761 mini
13. Barcode/NDC No: NA	14. Supersedes Item code No: PM04313001
15. Revision No: 01	16. A/W File name:Z:\Cinacalcet\Private Market\02\CINACALCET 30-60 mg PIL - PM04313002.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
21/05/2024	Vanita Rajool	21/05/24	23/05/24	23/05/24	23/05/24

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	PM04313001	20/04/24	Not Implemented
2) Leaflet last revision date is mentioned.	PM04313002		

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