Front Top
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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VEXICOP 100, hard capsules
VEXICOP 200, hard capsules
Celecoxib
Contains sugar (lactose monohydrate 16,9 mg in **VEXICOP 100** and 33,8 mg in **VEXICOP 200**)

Read all of this leaflet carefully before you start taking VEXICOP
- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **VEXICOP** 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 **VEXICOP** is and what it is used for
2. What you need to know before you take **VEXICOP**
3. How to take **VEXICOP**
4. Possible side effects
5. How to store **VEXICOP**
6. Contents of the pack and other information

1. What VEXICOP is and what it is used for

VEXICOP belongs to a group of medicines called nonsteroidal anti-inflammatory drugs (NSAIDs), and specifically a sub-group known as cyclooxygenase-2 (COX-2) inhibitors.

Your body makes substances called prostaglandins. Some prostaglandins may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. **VEXICOP** acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.
VEXICOP is used in adults for the relief of signs and symptoms of rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis (progressive stiffening of the spine).
VEXICOP is also used in the treatment of pain following an operation, including dental surgery, musculoskeletal pain, primary dysmenorrhoea (painful menstrual periods).

2. What you need to know before you take VEXICOP

Do not take VEXICOP:
- if you are hypersensitive (allergic) to celecoxib or any of the ingredients of **VEXICOP** (see **section 6 "What this product contains"**);
- if you have had an allergic reaction to a group of medicines called "sulphonamides" (medicines that prevent the growth of bacteria);
- if you have severe liver disease**;**
- if you have severe kidney disease;
- if you have had allergic reactions such as asthma, nose polyps, severe nasal congestion, or an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing from aspirin or other NSAIDs (anti-inflammatory and pain-relieving medicines, such as diclofenac, ibuprofen);
- if you have established ischaemic heart disease, or cerebrovascular disease, e.g. you have been diagnosed with a heart attack, stroke, or blockages of blood vessels to the heart or brain;
- if you are about to have coronary artery bypass graft surgery;
- if you currently have an ulcer in your stomach or intestines, or if you are bleeding in your stomach or intestines (you may notice that you have black sticky stools or bloody diarrhoea);
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease;
- if you are pregnant or it is possible that you could become pregnant;
- if you are breastfeeding.

VEXICOP
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Talk to your doctor or pharmacist before taking **VEXICOP**:
Take special care with **VEXICOP**:
- if you smoke, have diabetes, high blood cholesterol;
- if you have had a serious allergic reaction or a serious skin reaction to any medicines;
- if you have previously had an ulcer or bleeding in your stomach or intestines. (**Do not take VEXICOP** if you currently have an ulcer or bleeding in your stomach or intestine);
- if you are taking corticosteroid medicines (for example prednisone);
- if you are taking aspirin (even at low dose for heart protective purposes);
- if you use medicines to reduce blood clotting (e.g. warfarin/warfarin like anticoagulants or novel oral anti-clotting medicines, e.g. apixaban).
- if you are taking **VEXICOP** at the same time as other non-aspirin NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided;
- if you have fluid retention (such as swollen ankles and feet);
- if you have heart failure or other heart problems;
- if you have high blood pressure;
- if your liver or kidneys are not working well, as your doctor may want to keep a regular check on you;
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (medicines used to get rid of excess fluid in the body);
- if you feel ill due to an infection, or think you have an infection, as **VEXICOP** may mask a fever or other signs of infection and inflammation. If you are above 65 years of age your doctor will want to monitor you regularly.

The consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems.
VEXICOP may lead to an increase in blood pressure. Your doctor may want to monitor your blood pressure on a regular basis.
Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome or requiring liver transplant), have been reported with celecoxib. Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment.
Other medicines and VEXICOP
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
Before you take **VEXICOP**, make sure your doctor knows if you are taking the following medicines:
- Warfarin (used to prevent blood from clotting)
- ACE inhibitors, angiotensin II receptor antagonists, beta blockers (used for high blood pressure and heart failure)
- Diuretics (used to treat fluid retention)
- Ciclosporin and tacrolimus (used for immune system suppression e.g. after transplants)
- Aspirin (used for pain and fever). **VEXICOP** can be taken with low dose aspirin (75 mg or less daily). Ask your doctor for advice before taking both medicines together.

VEXICOP has no antiplatelet effect and is therefore not a substitute for aspirin for prevention of thrombosis
- Neuroleptics (used to treat some mental disorders)
- Medicines for anxiety (diazepam) or to treat depression (citalopram, imipramine)
- Medicines to treat an irregular heartbeat (amiodarone, quinidine)
- Dextromethorphan (used to treat coughs)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Lithium (used to treat some types of depression)
- Oral contraceptives
- Glibenclamide, tolbutamide (medicines used in the management of type 2 diabetes)
- Phenytoin, a medicine used in epilepsy (seizure disorder)
- Fluconazole (used to treat fungal infection)
- Rifampicin (used to treat bacterial infections)
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression)
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)
- Ketoconazole (an antifungal medicine)
- Antacids (used for heartburn).

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **VEXICOP**.

Pregnancy
VEXICOP must not be used by women who are pregnant or can become pregnant (i.e. women of childbearing potential who are not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with **VEXICOP** you should discontinue the treatment and contact your doctor for alternative treatment.

Breastfeeding
VEXICOP must not be used during breastfeeding.

Fertility
NSAIDs, including **VEXICOP**, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines
You should be aware of how you react to **VEXICOP** before you drive or operate machinery. If you feel dizzy or drowsy after taking **VEXICOP**, do not drive or operate machinery until these effects wear off.

VEXICOP contains lactose
VEXICOP contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **VEXICOP**.

3. How to take VEXICOP

Do not share medicines prescribed for you with any other person.
Always take **VEXICOP** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
If you think or feel that the effect of **VEXICOP** is too strong or too weak, talk to your doctor or pharmacist.
Use the lowest effective dose for the shortest possible time.
Your doctor will tell you what dose you should take.
The recommended dose for osteoarthritis is 200 mg taken as a single dose, or as two divided doses.
The recommended dose for rheumatoid arthritis is 100 mg or 200 mg twice daily.
The recommended dose for pain following dental surgery is 100 mg or 200 mg twice daily.
The recommended dose for pain following an operation is 200 mg once daily.
The recommended dose for musculoskeletal pain is 200 mg twice daily.
The recommended dose for primary dysmenorrhoea is 400 mg initially, followed by an additional 200 mg on the first day if needed. On subsequent days, the recommended dose is 200 mg twice daily.
The recommended dose for ankylosing spondylitis is 200 mg daily, taken as a single dose or as 100 mg twice daily.
If you have liver problems, or if you weigh less than 50 kg, your doctor will recommend the lowest recommended dose.
Children:
No information is available on the use of **VEXICOP** in children and it is therefore not recommended for use in children.

Method of administration:
VEXICOP is for oral use. Swallow the capsules whole with a glass of water at any time of the day, with or without food. However, try to take each dose of **VEXICOP** at the same time each day. Do not chew or crush the granules.
Contact your doctor within two weeks of starting treatment if you do not experience any benefit.

If you take more VEXICOP than you should
You should not take more capsules than your doctor tells you to.
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 VEXICOP
If you forget to take a capsule, take it as soon as you remember.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking VEXICOP
Suddenly stopping your treatment with **VEXICOP** may lead to your symptoms getting worse. Do not stop taking **VEXICOP** unless your doctor tells you to. Your doctor may tell you to reduce the dose over a few days before stopping completely.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

VEXICOP can have side effects.
Not all side effects reported for **VEXICOP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **VEXICOP**, please consult your doctor, pharmacist or other healthcare provider for advice.
If any of the following happens, stop taking VEXICOP 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.
- a serious skin reaction with rash, blistering or peeling of the skin.

These are all very serious side effects. If you have them, you may have had a serious reaction to **VEXICOP**. 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
- weakness or clumsiness of a hand, arm or leg, difficulties with speech and swallowing, vision problems and headache. These may be signs of a stroke or bleeding in the brain, which may be fatal.
- shortness of breath or difficulty breathing, sudden chest pain, cramping or tingling sensation up the left arm (heart attack)
- problems breathing, shortness of breath, chest pain. You may have a blood clot in the lung (pulmonary embolism) and will need urgent medical attention.
- throbbing or cramping pain in a leg, swelling in a leg, warm skin around painful area (deep vein thrombosis)
- severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood
- liver failure [symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow)]
- bladder or kidney infections. Some signs may be fever, chills, blood in the urine or frequent urination.
- acute renal failure/nephrotic syndrome (decreased urine output, swelling of legs, fatigue, foamy urine, loss of appetite)
- painful blisters, sensitive to touch (shingles)
- red, swollen, painful skin with fever (a bacterial skin infection, known as erysipelas)
- ache or burning pain in your abdomen (*Helicobacter pylori* infection).

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- infections of the airways such as sinusitis (swelling and redness of the nasal sinuses) or bronchitis (inflammation of the mucous membranes of the airways)
- worsening of existing allergies
- weight gain
- trouble sleeping
- dizziness, abnormal muscle tension
- headache
- high blood pressure, worsening of existing high blood pressure. You may not know that you have high blood pressure unless you have your blood pressure tested.
- runny nose, sore throat, shortness of breath
- nausea (feeling sick), vomiting (being sick)
- indigestion, windiness, pain on stomach
- problem swallowing
- sore teeth
- skin rash, itching skin
- accidental injury
- flu-like illness
- keeping fluid back in the body tissues, with swollen ankles, legs and/or hands.

Less frequent side effects
- inflammation or infection of the inner ear (dizziness or feeling that everything is spinning around you)
- infection of the gums
- blood disorders, such as anaemia (too few red blood cells or their haemoglobin content is too low), leukopenia (a lowered white blood cell count) or thrombocytopenia (deficiency of platelets in the blood)*
  * You will only know that you have these disorders if your doctor orders blood tests. See your doctor if you are pale and tired, get more infections than usual or have difficulty stopping bleeding, or if you have unexpected bruising.
- increased sodium in blood, increased potassium in blood (determined by blood tests)
- feeling tired, confused
- feeling anxious or depressed
- seeing or hearing things that do not exist (hallucinations)
- blurred vision, eye inflammation and bloodshot eyes, vitreous floaters (seeing spots or strings that move when you move your eyes), bleeding in an eye, painful eyes
- ringing in the ears, above normal hearing sense, voice disorder
- irregular heart rhythm, increased heart rate
- flushing, inflammation of a blood vessel (you may feel unwell with fever, sweats and tiredness)
- tightness in the chest with coughing and wheezing (bronchospasm)
- shortness of breath, cough, fatigue (inflammation of the lung tissues - pneumonitis)
- abdominal pain, cramping, bloating, constipation
- mouth ulcers, numbness, burning sensation in the mouth (stomatitis)
- hair loss
- muscle spasms (leg cramps), muscle pain
- lower limb fracture
- kidney function disorders (shown by laboratory tests)
- frequent urination during the night (nocturia)
- menstrual disorders
- swollen face
- chest pain.

Frequency unknown
- sleepiness
- abnormal skin sensations (tingling or tickling or itching or burning)
- problems with coordination and speech (ataxia)
- no sense of smell or taste, or taste affected
- worsening of existing epilepsy (seizure disorder)
- female fertility decreased
- vaginal bleeding
- tender breasts.

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, pharmacist or nurse. 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 **VEXICOP**.

5. How to store VEXICOP

Store at or below 25 °C (room temperature). Protect from light and moisture.
Store all medicines out of reach of children.
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 the pack and other information

What VEXICOP contains
The active substance is celecoxib.
Each hard gelatine capsule contains 100 mg or 200 mg of celecoxib.
The other ingredients are: crospovidone, hydroxypropylcellulose, magnesium stearate, povidone, sodium lauryl sulfate. Hard gelatin capsule containing gelatin, sodium lauryl sulfate, titanium dioxide (E171), blue edible printing ink for **VEXICOP 100** and yellow edible printing ink for **VEXICOP 200**.
Contains sugar: lactose monohydrate 16,9 mg in **VEXICOP 100** and 33,8 mg in **VEXICOP 200**.

What VEXICOP looks like and contents of the pack
VEXICOP 100:
Size '4' capsules, containing white to off white powder, having white opaque cap and white opaque body with 'C5' imprinted on a blue band on the cap and '100 mg' imprinted on a blue band on the body.

VEXICOP 200:
Size '2' capsules, containing white to off white powder, having white opaque cap and white opaque body with 'C6' imprinted on a yellow band on the cap and '200 mg' imprinted on a yellow band on the body.

Blister pack:
Plain, silver coloured 25 µ Aluminium foil/ 6-8 gsm HSL as the lidding material and clear, transparent PVC/PVdC 250 µ/ 60 gsm as the forming material, packed in a pre-printed unit carton with 10, 20, 30 or 60 capsules.
*Not all pack sizes will be marketed

Holder of Certificate of Registration
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Registration numbers
VEXICOP 100 : 49/3.1/0047
VEXICOP 200 : 49/3.1/0048

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.

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335 mm

380 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

VEXICOP 100, harde kapsules
VEXICOP 200, harde kapsules
Selekoksib
Bevat suiker (16,9 mg laktosemonohidraat in **VEXICOP 100** en 33,8 mg in **VEXICOP 200**)

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

1. Wat VEXICOP is en waarvoor dit gebruik word

VEXICOP behoort aan 'n groep medisyne wat nie steroïedale anti-inflammatoriese middels (NSAIM's) genoem word, en spesifiek 'n subgroep bekend as sikloöksigenase-2 (COX-2) inhibeerders.

Jou liggaam maak stowwe wat prostaglandiene genoem word. Sommige prostaglandiene kan pyn en inflammasie veroorsaak. In toestande soos rumatoïede artritis en osteoartritis maak jou liggaam meer hiervan. **VEXICOP** werk deur die produksie van prostaglandiene te verminder en sodoende die pyn en inflammasie te verminder.
VEXICOP word gebruik in volwassenes vir die verligting van tekens en simptome van rumatoïede artritis, osteoartritis en ankiloserende spondilitis (progressiewe styfheid van die ruggraat).
VEXICOP word ook gebruik in die behandeling van pyn na 'n operasie, insluitend tandheelkundige chirurgie, muskuloskeletale pyn, primêre dismenoree (pynlike menstruasie periodes).

2. Wat jy behoort te weet voordat jy VEXICOP gebruik

Moet nie VEXICOP gebruik:
- Indien jy hipersensitief (allergies) vir selekoksib, of enige van die bestanddele van **VEXICOP** is (sien **afdeling 6 "Wat hierdie produk bevat"**).
- indien jy 'n allergiese reaksie gehad het op 'n groep medisyne wat "sulfoonamiede" genoem word (medisyne wat die groei van bakterieë voorkom);
- indien jy ernstige lewersiekte het;
- indien jy ernstige niersiekte het;
- indien jy allergiese reaksies soos asma, neuspoliepe, erge neusverstopping, of 'n jeukende veluitslag, swelling van die gesig, lippe, tong of keel, asemhalingsprobleme of asemgefluit gehad het van aspirien of ander NSAIM's (anti-inflammatories en pynverligtende medisyne, soos diklofenak, ibuprofen);
- Gevestigde isgemiese hartsiekte, of serebrovaskulêre siekte, bv. jy is gediagnoseer met 'n hartaanval, beroerte, of blokkasies van bloedvate na die hart of brein;
- indien jy op die punt is om hartslagaaromleidings chirurgie te ondergaan;
- indien jy tans 'n ulkus in jou maag of ingewande het, of as jy in jou maag of ingewande bloei (jy mag dalk opmerk dat jy swart taai stoelgang of bloederige diaree het);
- indien jy 'n inflammatoriese siekte van die ingewande het soos ulseratiewe kolitis of Crohn se siekte;
- indien jy swanger is of dit moontlik is dat jy swanger kan raak;
- as jy borsvoed.

Praat met jou dokter of apteker voordat jy **VEXICOP** neem:
Wees veral versigtig met **VEXICOP**:
- indien jy rook, diabetes het, hoë bloedcholesterol;
- indien jy 'n ernstige allergiese reaksie of 'n ernstige velreaksie op enige medisyne gehad het;
- indien jy voorheen 'n ulkus of bloeding in jou maag of ingewande gehad het. (**Moet nie VEXICOP neem** as jy tans 'n ulkus of bloeding in jou maag of ingewande het nie);
- indien jy kortikosteroïed medisyne (byvoorbeeld prednisoon) gebruik;
- indien jy aspirien neem (selfs teen 'n lae dosering vir hartbeskermings doeleindes);
- indien jy medisyne gebruik om bloedstolling te verminder (bv. warfarien/warfarien-agtige antikoagulante of nuwe orale anti-stollings middels, bv. apiksabaan).
- Indien jy **VEXICOP** gelyktydig saam met ander nie-aspirien NSAIM's soos ibuprofen of diklofenak neem. Die gebruik van hierdie medisyne saam moet vermy word;
- as jy vogretensie het (soos geswelde enkels en voete);
- indien jy hartversaking of ander hartprobleme het;
- as jy hoë bloeddruk het;
- indien jou lewer of niere nie goed werk nie, aangesien jou dokter moontlik gereeld na jou sal wil kyk;
- as jy gedehidreer is, byvoorbeeld as gevolg van siekte, diaree of die gebruik van diuretika (medisyne wat gebruik word om van oortollige vloeistof in die liggaam ontslae te raak);
- indien jy siek voel as gevolg van 'n infeksie, of vermoed dat jy 'n infeksie het, aangesien **VEXICOP** 'n koors of ander tekens van infeksie en ontsteking kan maskeer. Indien jy ouer as 65 jaar is, sal jou dokter jou gereeld wil monitor.

Die gebruik van alkohol en NSAIM's kan die risiko van gastroïntestinale probleme verhoog.
VEXICOP kan lei tot 'n toename in bloeddruk. Jou dokter sal moontlik jou bloeddruk op 'n gereelde basis wil monitor.
Sommige gevalle van ernstige lewerreaksies, insluitend ernstige lewerontsteking, lewerskade, lewerversaking (sommige met noodlottige uitkoms of wat leweroorplanting vereis), is met selekoksib aangemeld. Van die gevalle wat tyd tot aanvang gerapporteer het, het die meeste ernstige lewerreaksies binne een maand na aanvang van behandeling plaasgevind.

Ander medisyne en VEXICOP
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in).
Voordat jy **VEXICOP** neem, maak seker dat jou dokter weet indien jy die volgende medisyne gebruik:
- Warfarien (word gebruik om te voorkom dat bloed stol)
- AOE-inhibeerders, angiotensien II reseptor antagoniste, betablokkers (gebruik vir hoë bloeddruk en hartversaking)
- Diuretika (gebruik om vogretensie te behandel)
- Siklosporien en takrolimus (gebruik vir onderdrukking van die immuunstelsel, bv. ná oorplantings)
- Aspirien (gebruik vir pyn en koors). **VEXICOP** kan saam met 'n lae dosering aspirien (75 mg of minder per dag) geneem word. Vra jou dokter vir advies voordat jy albei medisyne saam neem
- **VEXICOP** het geen bloedplaatjie-effek nie en is dus nie 'n plaasvervanger vir aspirien vir die voorkoming van trombose nie
- Neuroleptika (gebruik om sekere geestesversteurings te behandel)
- Medisyne vir angs (diasepam) of om depressie te behandel (sitalopram, imipramien)
- Medisyne om 'n onreëlmatige hartklop te behandel (amiodaroon, kinidien)
- Dekstrometorfaan (gebruik om hoes te behandel)
- Metotreksaat (gebruik om rumatoïede artritis, psoriase en leukemie te behandel).
- Litium (gebruik om sommige tipes van depressie te behandel)
- Orale voorbehoedmiddels
- Glibenklamied, tolbutamied (medisyne wat gebruik word in die behandeling van tipe 2-diabetes)
- Fenitoïen, 'n middel wat gebruik word in epilepsie (aanvalversteuring)
- Flukonasool (gebruik om swaminfeksie te behandel)
- Rifampisien (gebruik om bakteriële infeksies te behandel)
- Karbamasepien (gebruik om epilepsie/aanvalle en sommige vorme van pyn of depressie te behandel)
- Barbiturate (gebruik om epilepsie/aanvalle en sommige slaapversteurings te behandel)
- Ketokonasool ('n swambestrydende middel)
- Teensuurmiddels (gebruik vir sooibrand)

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, dink dat jy dalk swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy **VEXICOP** neem.

Swangerskap
VEXICOP moet nie tydens deurlopende behandeling deur vrouens wat swanger is of swanger kan raak (d.w.s. vrouens van kinderbarende potensiaal wat nie voldoende voorbehoeding gebruik nie) geneem word nie. Indien jy swanger raak tydens behandeling met **VEXICOP** moet jy die behandeling staak en jou dokter kontak vir alternatiewe behandeling.

Borsvoeding
VEXICOP moet nie tydens borsvoeding gebruik word nie.

Fertiliteit
NSAIM's, insluitend **VEXICOP**, kan dit moeiliker maak om swanger te raak. Jy moet jou dokter vertel indien jy van plan is om swanger te raak of indien jy probleme ondervind om swanger te raak.

Bestuur en gebruik van masjinerie
Jy moet bewus wees van hoe jy op **VEXICOP** reageer, voordat jy bestuur of masjinerie gebruik. Indien jy duiselig of lomerig voel nadat jy **VEXICOP** geneem het, moet nie bestuur of masjinerie gebruik totdat hierdie effekte verdwyn het nie.

VEXICOP bevat laktose
VEXICOP bevat laktose ('n soort suiker). Indien jou dokter vir jou gesê het dat jy 'n onverdraagsaamheid teenoor sommige suikers het, moet jy jou dokter kontak voordat jy **VEXICOP** neem.

3. Hoe om VEXICOP te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **VEXICOP** presies soos jou dokter of apteker vir jou gesê het. Vra vir jou dokter of apteker indien jy onseker is.
Indien jy dink of voel dat die effek van **VEXICOP** te sterk of te swak is, praat met jou dokter of apteker.
Gebruik die laagste effektiewe dosering vir die kortste moontlike tyd.
Jou dokter sal jou vertel watter dosering jy moet neem.
Die aanbevole dosis vir osteoartritis is 200 mg geneem as 'n enkele dosering, of as twee verdeelde dosisse.
Die aanbevole dosis vir rumatoïede artritis is 100 mg of 200 mg twee keer per dag.
Die aanbevole dosis vir pyn na tandheelkundige chirurgie is 100 mg of 200 mg twee keer per dag.
Die aanbevole dosis vir pyn na 'n operasie is 200 mg een keer per dag.
Die aanbevole dosis vir muskuloskeletale pyn is 200 mg twee keer per dag.
Die aanbevole dosis vir primêre dismenoree is aanvanklik 400 mg, gevolg deur 'n bykomende 200 mg op die eerste dag, indien nodig. Op die daaropvolgende dae is die aanbevole dosis 200 mg twee keer per dag.
Die aanbevole dosis vir ankiloserende spondilitis is 200 mg daagliks, geneem as 'n enkele dosering of as 100 mg twee keer per dag.
Indien jy lewerprobleme het, of as jy minder as 50 kg weeg, sal jou dokter die laagste aanbevole dosis aanbeveel.
Kinders:
Geen inligting is beskikbaar oor die gebruik van **VEXICOP** in kinders nie, en dit word dus nie aanbeveel vir gebruik in kinders nie.
Metode van toediening:
VEXICOP is vir orale gebruik. Sluk die kapsules heel met 'n glas water op enige tyd van die dag, met of sonder kos. Probeer egter om elke dosis van **VEXICOP** elke dag op dieselfde tyd te neem. Moet nie die korrels kou of vergruis nie.
Kontak jou dokter binne twee weke nadat jy met behandeling begin het indien jy geen verbetering ervaar nie.

Indien jy meer VEXICOP geneem het as wat jy behoort te neem
Jy moet nie meer kapsules neem as wat jou dokter jou beveel het om te doen nie.
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 VEXICOP te neem
Indien jy vergeet om 'n kapsule te neem, neem dit sodra jy onthou.
Moet nie 'n dubbele dosis neem om vir vergete individuele dosisse op te maak nie.

Indien jy ophou om VEXICOP te neem
Om jou behandeling met **VEXICOP** skielik te staak, kan daartoe lei dat jou simptome vererger. Moet nie ophou om **VEXICOP** te neem nie, tensy jou dokter jou beveel om dit te doen. Jou dokter kan moontlik aanbeveel dat jy die dosis oor 'n paar dae verminder, voordat jy heeltemal ophou.
Indien jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

4. Moontlike newe-effekte

VEXICOP kan newe-effekte hê.
Nie al die newe-effekte wat vir **VEXICOP** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige onaangename gevolge ondervind terwyl jy **VEXICOP** gebruik, kontak jou gesondheidsorgverskaffer vir advies.
Indien enige van die volgende gebeur, hou op om VEXICOP te gebruik en sê onmiddellik vir jou dokter, 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;
- 'n ernstige velreaksie met uitslag, blaasvorming of afskilfering van die vel.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit ervaar, kan dit wees dat jy 'n ernstige reaksie teen **VEXICOP** gehad het. Jy kan dringende mediese aandag of hospitalisasie nodig hê.

Sê onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- swakheid of lompheid van 'n hand, arm of been, probleme met spraak en sluk, probleme met visie en hoofpyn. Hierdie kan tekens wees van 'n beroerte of bloeding in die brein, wat noodlottig kan wees.
- kortasem of moeilike asemhaling, skielike borskaspyn, krampe of 'n tintelende sensasie op in die linkerarm (hartaanval)
- probleme met asemhaling, kortasem, borskaspyn. Jy kan moontlik 'n bloedklont in die long hê (pulmonêre embolisme) en sal dringende mediese aandag nodig hê.
- kloppende of krampende pyn in 'n been, swelling in 'n been, warm vel rondom pynlike area (diep veneuse trombose)
- erge maagpyn of enige teken van bloeding in die maag of ingewande, soos ontlasting van swart of bloedbevlekte stoelgang, of braking van bloed
- lewerversaking (simptome kan naarheid (siek voel), diaree, geelsug (jou vel of die wit van jou oë lyk geel) insluit)
- blaas- of nierinfeksies. Sommige tekens kan koors, koue rillings, bloed in die uriene of gereelde urinering wees.
- akute nierversaking/nefrotiese sindroom (verminderde urien opbrengs, swelling van bene, moegheid, skuimerige uriene, verlies aan eetlus)
- pynlike blase, sensitief vir aanraking (gordelroos)
- rooi, geswelde, pynlike vel met koors ('n bakteriële velinfeksie, bekend as erisipelas)
- aanhoudende pyn of brandpyn in jou buik (*Helicobacter pylori* infeksie).

Hierdie is alles ernstige newe-effekte. Jy benodig moontlik dringende mediese hulp.

Sê vir jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- infeksies van die lugweë, soos sinusitis (swelling en rooiheid van die nasale sinusse) of brongitis (ontsteking van die slymvliese van die lugweë)
- verergering van bestaande allergieë
- toename in gewig
- probleme om te slaap
- duiseligheid, abnormale spierspanning
- hoofpyn
- hoë bloeddruk, verergering van bestaande hoë bloeddruk. Jy weet moontlik nie dat jy hoë bloeddruk het nie, tensy jy jou bloeddruk laat toets
- loopneus, seer keel, kortasem.
- naarheid (siek voel), braking (siek wees)
- slegte spysvertering, winderigheid, pyn op die maag
- probleme met sluk
- seer tande
- veluitslag, jeukerige vel
- toevallige besering
- griepagtige siekte
- hou vog terug in die liggaamsweefsel, met geswelde enkels, bene en/of hande.

Minder gereelde newe-effekte:
- ontsteking of infeksie van die midde-oor (duiseligheid of voel asof alles om jou draai)
- infeksie van die tandvleis
- bloedafwykings, soos anemie (te min rooibloedselle of hulle hemoglobieninhoud is te laag), leukopenie ('n verlaagde witbloedseltelling) of trombositopenie (tekort aan bloedplaatjies in die bloed) *

* Jy sal slegs weet of jy hierdie afwykings het indien jou dokter bloedtoetse aanvra. Spreek jou dokter indien jy bleek en moeg is, meer infeksies as gewoonlik kry of probleme het om bloeding te stop, of indien jy onverwagte kneusing het.
- verhoogde natrium in bloed, verhoogde kalium in bloed (deur bloedtoetse vasgetsel)
- moeg, verward voel
- angstig of depressief voel
- goed sien of hoor wat nie bestaan nie (hallusinasies)
- dowwe visie, oogontsteking en bloedbelope oë, glasagtige drywers (sien kolle of stringe wat beweeg wanneer jy jou oë beweeg), bloeding in 'n oog, pynlike oë
- gesuis in die ore, bo normaal gehoorsin, stemversteuring
- onreëlmatige hartritme, verhoogde harttempo
- blosing, inflammasie van 'n bloedvat (jy kan siek voel met koors, sweet en moegheid)
- beklemming in die bors met hoes en hyg (brongospasma)
- kortasem, hoes, vermoeidheid (ontsteking van die longweefsel - longontsteking)
- abdominale pyn, krampe, opgeblasenheid, hardlywigheid
- mondsere, gevoelloosheid, brandende sensasie in die mond (stomatitis)
- haarverlies
- spierspasmas (beenkrampe), spierpyn
- onderlededmaat fraktuur
- nierfunksie versteurings (bewys deur laboratoriumtoetse)
- dikwelse urinering gedurende die nag (nokturie)
- menstruasie versteurings
- geswelde gesig
- borskaspyn.

Onbekende frekwensie:
- slaperigheid
- abnormale velsensasies (tinteling of kielie of jeuk of brand)
- probleme met koördinasie en spraak (ataksie)
- geen reuk- of smaaksin nie, of aangetasde smaak
- verergering van bestaande epilepsie (aanvalversteuring)
- afname in vroulike vrugbaarheid
- vaginale bloeding
- teer borste.

Indien jy enige newe-effek opmerk wat nie in hierdie inligtingstuk genoem word nie, moet jy asseblief jou dokter of apteker in kennis stel.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter, apteker of verpleegkundige. Jy kan ook newe-effekte aan SAHPRA rapporteer via 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 **VEXICOP**.

5. Hoe om VEXICOP te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig en vog.
Bewaar alle medisyne buite bereik van kinders.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in die badkamer bêre nie.
Moet nie ná 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 VEXICOP bevat
Die aktiewe bestanddeel is selekoksib.
Elke harde gelatien kapsule bevat 100 mg of 200 mg van selekoksib.
Die ander bestanddele is: kruispovidoon, hidroksipropielsellulose, magnesiumstearaat, povidoon, natriumlaurielsulfaat. Harde gelatien kapsule wat gelatien, natriumlaurielsulfaat, titaandioksied (E171), blou eetbare drukink vir **VEXICOP 100** en geel eetbare drukink vir **VEXICOP 200** bevat.
Bevat suiker: 16,9 mg laktosemonohidraat in **VEXICOP 100** en 33,8 mg in **VEXICOP 200**.

Hoe VEXICOP lyk en inhoud van die pak
VEXICOP 100:
Grootte '4' kapsules, wat wit tot naaswit poeier bevat, met 'n wit ondeursigtige doppie en wit ondeursigtige romp met 'C5' gedruk op 'n blou band op die doppie en '100 mg' gedruk op 'n blou band op die romp.

VEXICOP 200:
Grootte '2' kapsules, wat wit tot naaswit poeier bevat, met 'n wit ondeursigtige doppie en wit ondeursigtige romp met 'C6' gedruk op 'n geel band op die doppie en '200 mg' gedruk op 'n geel band op die romp.

Stulpverpakking:
Gewone, silwerkleurige 25 µ aluminiumfoelie/ 6-8 gsm HSL as die dekmateriaal en helder, deursigtige PVC/PVdC 250 µ/ 60 gsm as die vormingsmateriaal, verpak in 'n voorafgedrukte eenheidskarton met 10, 20, 30 of 60 kapsules.
*Nie alle verpakkings groottes sal bemark word 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 is laas hersien in
07 Desember 2021

Registrasienommer
VEXICOP 100: 49/3.1/0047
VEXICOP 200: 49/3.1/0048

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.

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Removal of English and African PI as per customer requirement and dimension change in PIL.

1. Product: VEXICOP 100 / 200 (Celecoxib Capsule 100 / 200 mg)					
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: 380 (L) x 335 (W) mm**			
9. Design / Style: Booklet		**10. Item code No.: PM04340086**			
11. Artwork has been made: Actual Size		**12. Pharma code No.: 40496 mini**			
13. Barcode/NDC no: NA		**14. Supersedes Item code No: PM03913501**			
15. Revision no: 01		**16. A/W File name: Z:\South Africa\Celecoxib\SA Private Market\01\Celecoxib 100-200 mg PIL - PM04340086.cdr**			
Approved By:		**17. Location: Baddi**			
PRD	**M.A. HOLDER**	**MEDICAL/RAD**	**QC**	**PRODN**	**QA**
	25/09/2025				

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.

Format No: FRM/SOP/CO/CQA/021/03-003

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03913501	16/08/22	12/10/22
2) Removal of English and African PI as per customer requirement and dimension change in PIL.	PM04340086		