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Patient Information Leaflet

SCHEDULING STATUS: S4

VCIDE® 50 FC, film-coated tablet
VCIDE® 200 FC, film-coated tablet
Voriconazole
Contains sugar (lactose monohydrate)
Each **VCIDE 50 FC** tablet contains 58,77 mg lactose monohydrate and each **VCIDE 200 FC** tablet contains 235,08 mg lactose monohydrate.

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

1. What VCIDE is and what it is used for
VCIDE is an antifungal medicine. It works by killing or stopping the growth of the fungi that cause infections.
VCIDE is used for the treatment of patients (adults and children over the age of 2) with:
- invasive aspergillosis (a serious type of fungal infection due to *Aspergillus sp.*),
- serious invasive *Candida* sp. infections (including *C. krusei*),
- serious fungal infections caused by *Scedosporium sp.* or *Fusarium sp.* (two different species of fungi).

VCIDE may also be used for the prevention of fungal infections in high risk patients, for example bone marrow transplant recipients, where another antifungal medicine cannot be used.
VCIDE should only be used under the supervision of a doctor.

2. What you need to know before you take VCIDE
Do not take VCIDE:
- if you are hypersensitive (allergic) to voriconazole or any ingredient in **VCIDE** (listed in section 6);
- if you have prolonged QT-syndrome (a heart rhythm disorder);
- if your liver function is severely affected;
- if you are pregnant or breastfeeding.

It is very important that you inform your doctor or pharmacist if you are taking or have taken any other medicines, even those that are obtained without a prescription, or herbal medicines. There are many medicines that must **not** be taken during your course of **VCIDE** treatment:
- Terfenadine (used for allergy)
- Astemizole (used for allergy)
- Cisapride (used for stomach problems)
- Pimozide (used for treating mental illness)
- Quinidine (used for irregular heartbeat)
- Rifampicin (used for treating tuberculosis)
- Carbamazepine (used to treat seizures)
- Phenobarbital (used for severe insomnia and seizures)
- Ritonavir (used for treating HIV) in doses of **400 mg** and more, twice daily
- Ergot alkaloids (e.g., ergotamine, dihydroergotamine; used for migraine)
- Sirolimus (used in transplant patients)
- Rifabutin (used for treating tuberculosis)
- St. John's Wort (herbal supplement).

Warnings and precautions
Tell your doctor, pharmacist or healthcare provider before you take **VCIDE**, if you:
- are allergic to other azole type medicines (these are antifungal medicines, for example, fluconazole or ketoconazole. Ask your doctor or pharmacist if you are unsure);
- are suffering from liver disease or have ever suffered from it. If you have liver disease, your doctor may prescribe a lower dose of **VCIDE**. Your doctor should also monitor your liver function while you are being treated with **VCIDE** by doing blood tests;
- you are known to have cardiomyopathy (diseased heart muscle), irregular heartbeat, slow heart rate or an abnormality of electrocardiogram (ECG) called 'long QTc syndrome' (see section 2 "Do not take **VCIDE**");
- have electrolyte disturbances such as low potassium, calcium or magnesium;
- have a kidney disease. Your doctor should monitor your renal function while you are being treated with **VCIDE** by doing blood tests.

You should also know that:
You should avoid any sunlight and sun exposure while being treated. It is important to cover sun exposed areas of skin and use sunscreen with high sun protection factor (SPF), as an increased sensitivity of skin to the sun's UV rays can occur. These precautions are also applicable to children.
While being treated with **VCIDE**, tell your doctor immediately if you develop:
- sunburn
- severe skin rash or blisters
- bone pain.

If you develop skin disorders as described above, your doctor may refer you to a dermatologist, who after consultation may decide that it is important for you to be seen on a regular basis. There is a small chance that skin cancer could develop with long-term use of **VCIDE**.
VCIDE can cause problems with your eyes and vision, including blurred vision and light sensitivity. You should wear sunglasses to protect your eyes from bright light.
If you had an organ transplant and receive **VCIDE**, you may have inflammation and pain in the bones. See your doctor as soon as possible. He/she will decide if you should continue treatment with **VCIDE** and will treat you as necessary.
Effective contraception must be used in women of childbearing potential.
Children
VCIDE is not recommended for use in children below the age of 2 years because there is insufficient data on safety and effectiveness in this age group.

Other medicines and VCIDE
Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines).
Some medicines, when taken at the same time as **VCIDE**, may affect the way **VCIDE** works or **VCIDE** may affect the way they work.
VCIDE must not be taken *if you are already taking any of the following list of medicines. Tell your doctor if you take:*
- Astemizole (used for allergy)
- Terfenadine (used for allergy)
- Cisapride (used for stomach problems)
- Pimozide (used for treating mental illness)
- Quinidine (used for irregular heartbeat)
- Carbamazepine (used to treat seizures)
- Phenobarbital (used for severe insomnia and seizures)
- Efavirenz (used for treating HIV) in doses of 400 mg and above once daily
- Ergot alkaloids (e.g., ergotamine, dihydroergotamine; used for migraine)
- Rifampicin (used for treating tuberculosis)
- Ritonavir (used for treating HIV) in doses of **400 mg** and more twice daily
- Rifabutin (used for treating tuberculosis)
- St. John's Wort (herbal supplement)
- Sirolimus (used in transplant patients).

*Tell your doctor if you are taking the following medicine, as treatment with **VCIDE** at the same time should be avoided if possible:*
- Ritonavir (used for treating HIV) in doses of **100 mg** twice daily.
- Phenytoin (used to treat epilepsy). If you are already being treated with phenytoin your blood concentration of phenytoin will need to be monitored during your treatment with **VCIDE** and your dose may be adjusted.

*Tell your doctor if you are taking any of the following medicines, as a dose adjustment or monitoring may be required to check that the medicines and / or **VCIDE** are still working as it should be:*
- Everolimus (used for treating advanced kidney cancer and in transplant patients)
- Fluconazole (used for fungal infections)
- Warfarin and other anticoagulants (e.g., phenprocoumon, acenocoumarol; used to slow down clotting of the blood)
- Benzodiazepines (for example, midazolam, triazolam) (used for severe insomnia and stress)
- Ciclosporin (used in transplant patients)
- Tacrolimus (used in transplant patients)
- Oxycodone and other long-acting opiates such as hydrocodone (used for moderate to severe pain)
- Methadone (used to treat heroin addiction)
- Non-steroidal anti-inflammatory drugs (e.g., ibuprofen, diclofenac) (used for treating pain and inflammation)
- Omeprazole (used for treating ulcers)
- Oral contraceptives (if you take **VCIDE** while using oral contraceptives, you may get side effects such as nausea and menstrual disorders)
- Alfentanil and fentanyl and other short-acting opiates such as sufentanil (painkillers used for surgical procedures)
- Statins (for example atorvastatin, simvastatin) (used for lowering cholesterol)
- Sulfonylureas (for example tolbutamide, glipizide, and glyburide) (used for diabetes)
- Vinca alkaloids (for example vincristine and vinblastine) (used in treating cancer)
- Other protease inhibitors (for example, saquinavir, amprenavir and nelfinavir)
- Non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz, delavirdine, nevirapine) (used for treating HIV) (some doses of efavirenz can NOT be taken at the same time as **VCIDE**)

Do not start taking or using a new medicine before you have discussed this with your doctor or pharmacist. Your doctor and pharmacist have more information on medicines to be careful with, or to avoid while you are given **VCIDE**.

Pregnancy and breastfeeding
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 **VCIDE**. Adequate information is not available on the use of **VCIDE** in pregnant women. Studies in animals have toxic effects on the developing foetus. The potential risk to humans is unknown. **VCIDE** should not be used during pregnancy.
You must use effective contraception if you are of childbearing age. Contact your doctor immediately if you become pregnant while being treated with VCIDE.
It is not known if **VCIDE** is excreted in breastmilk. You should not breastfeed your baby if you are taking **VCIDE**.

Driving and using machines
VCIDE may cause blurring of your vision and you may feel dizzy (see section 4). If this happens, you should not drive or handle tools or machinery.

VCIDE contains lactose
VCIDE contains lactose monohydrate (a sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take VCIDE
Do not share medicines prescribed for you or your child with any other person.
Always take **VCIDE** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Your doctor will decide what dose you should receive for your condition and also for how long you need to receive it. The dose and duration of treatment will depend on how your body and the infection reacts on the treatment.
Depending on your response to treatment, your doctor may increase or decrease your dose.
Take your tablet at least one hour before, or one hour after a meal. Swallow the tablet whole with some water.

Use in children and adolescents
Tablets must only be given if the child is able to swallow tablets.
Your child's doctor will work out the dose for your child, based on his/her mass.
He/she will tell you how long the treatment with **VCIDE** will last.
Take your tablet at least one hour before, or one hour after a meal. Swallow the tablet whole with some water.
Continue taking **VCIDE** until your doctor tells you to stop. Do not stop treatment early because your infection may not be cured. Patients with a weakened immune system or those with difficult infections may require long term treatment to prevent the infection from returning.
If you have the impression that the effect of **VCIDE** is too strong or too weak, tell your doctor or pharmacist.

If you take more VCIDE than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VCIDE
Do not take a double dose to make up for forgotten individual doses.

If you stop taking VCIDE
It is important that you finish your treatment as prescribed by your doctor.
Do not stop taking **VCIDE** just because you feel better. If you stop taking treatment before the course is completed, the fungus causing the disease may become resistant to **VCIDE** and your disease will get worse.

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

If any of the following happens, stop using VCIDE and tell your doctor immediately:
- Serious allergic reactions, including a shock reaction. You may have swelling of the tongue and/or throat, difficulty in swallowing, difficulties in breathing, facial swelling, severe dizziness with very fast heartbeat and heavy sweating.
- Allergic skin reactions (sometimes severe), including rapid swelling (oedema) of the dermis, subcutaneous tissue, mucosa and submucosal tissues, itchy or sore patches of thick, red skin with silvery scales of skin, irritation of the skin and mucous membranes, life threatening skin condition that causes large portions of the epidermis, the skin's outermost layer, to detach from the layers of skin below.

These are all very serious side effects. If you have them, you may have had a serious reaction to **VCIDE**. 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:
- Jaundice (yellowing of the eyes or skin, dark urine, upper stomach pain), liver failure, gallbladder disease, gallstones.
- Deterioration of brain function that is a serious complication of liver disease.
- Inflammation of the pancreas (abdominal pain, fever, rapid pulse, nausea, shivering).
- Severe diarrhoea and nausea with fever and weakness. This is a serious condition for which you may need urgent treatment.
- Heart rhythm disturbances, including very fast heartbeat, very slow heartbeat, conduction problems (sometimes life threatening), fainting.
- Double vision, serious conditions of the eye including pain and inflammation of the eyes and eyelids, abnormal eye movement, damage to the optic nerve resulting in vision impairment, optic disc swelling.
- Disorder of blood clotting system (clotting in the blood vessels).
- Guillain-Barre syndrome (the body's immune system attacks part of the peripheral nervous system, with resulting muscle weakness, beginning in the feet and hands).
- Kidney failure, inflammation in the kidney, blood in the urine, problems urinating, changes in kidney function tests, proteins in the urine.

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
- Sinusitis (infection of the nasal passages)
- Low numbers of some types, including severe, of red (sometimes immune-related) and/or white blood cells (sometimes with fever), low numbers of cells called platelets that help the blood to clot
- You get more infections than usual. This could be because of a decrease in white blood cells. Your doctor will confirm this with a blood test
- Low blood sugar, low blood potassium or low sodium in the blood (you will only know for sure that you have these deficiencies if you go for blood tests). Tell your doctor if you have muscle cramps and feel weak
- Easy or excessive bruising, superficial bleeding into the skin, unexpected excessive bleeding, particularly if you also take or receive blood thinning medicines such as warfarin
- Depression, problems falling asleep, anxiety, hallucinations (false perceptions)
- Sleepiness, feeling faint and/or dizzy
- Convulsions (fits or jerks), severe headache, loss of coordination
- Tingling or abnormal skin sensations, increase in muscle tone
- Bleeding in the eye
- Low blood pressure (you may feel faint or dizzy)
- Inflammation of a vein (phlebitis, a condition where the veins close to the surface of the body become swollen, tender, and red and may develop blood clots)
- Nausea (feeling sick), vomiting (being sick), diarrhoea (loose bowels), stomach pain, inflammation of the lips
- Constipation, indigestion
- Skin rashes, hair loss
- Back pain
- Feeling tired and generally weak.

Less frequent side effects
- Enlarged lymph glands (sometimes painful), failure of bone marrow, increased eosinophil
- Disorder of blood clotting system
- Overactive thyroid. If you have muscle weakness, have a rapid heartbeat and increased appetite, tell your doctor
- Underactive thyroid (some signs may be weight gain, fatigue and depression)
- Abnormal sense of taste
- Decreased sensitivity to touch
- Abnormal brain function, Parkinson-like symptoms, nerve injury resulting in numbness, pain, tingling or burning in the hands or feet
- Sudden behaviour changes, problems with thinking or speech
- Problems with balance or coordination, swelling of the brain
- Eye-rolling disorder where the eyes fix upwards
- Ringing in the ears, dizziness, hearing loss
- Inflammation of certain internal organs – pancreas and duodenum, swelling and inflammation of the tongue
- Inflammation of the thin tissue that lines the inner wall of the abdomen and covers the abdominal organ
- Bullous photosensitivity
- Freckles and pigmented spots
- Joint and muscle pains in the legs and arm
- Flu-like illness
- Increased blood cholesterol.

Other significant side effects whose frequency is not known, but should be reported to your doctor immediately:
- Skin cancer
- Inflammation of the tissue surrounding the bone
- Red, scaly patches or ring-shaped skin lesions that may be a symptom of an autoimmune disease called cutaneous lupus erythematosus.

Some side effects such as temporary blood, cholesterol, kidney or liver problems can only be detected when your doctor orders blood or urine tests to check your progress.
Sunburn or severe skin reaction following exposure to light or sun was experienced more frequently in children. If you or your child develops skin disorders, your doctor may refer you to a dermatologist, who after consultation may decide that it is important for you or your child to be seen on a regular basis. Elevated liver enzymes were also observed more frequently in children.
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 on the SAHPRA website:
https://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of **VCIDE**.

5. How to store VCIDE
Store all medicines out of reach of children.
Store in the original pack at or below 25 °C.
Do not use after the expiry date stated on the label and carton.
Bottles: Use within 30 days after first opening.
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 VCIDE contains
- The active substance is voriconazole.
  Each **VCIDE 50 FC** tablet contains 50 mg voriconazole and each **VCIDE 200 FC** tablet contains 200 mg voriconazole.
- The other ingredients are pregelatinised maize starch, lactose monohydrate, povidone K30, croscarmellose sodium, colloidal anhydrous silica and magnesium stearate. The tablet coating, Opadry II White OY-LS-28908, contains titanium dioxide (E171), lactose monohydrate, hypromellose (E464) and macrogol/PEG (E1521).

What VCIDE looks like and contents of the pack
Film-coated tablets.
VCIDE 50 FC is presented as a white to off-white round biconvex film-coated tablet with code V50 on one side.
VCIDE 200 FC is presented as a white to off-white oval biconvex film-coated tablet with code V200 on one side.
The tablets are packed in:
Cartons containing transparent PVC/aluminium foil blisters of 2, 7, 10, 14, 20, 28, 30, 50, 56 or 100 film-coated tablets, together with a leaflet.
Cartons containing white opaque HDPE bottles, with child-resistant polypropylene screw caps and induction seal liners, with 30 film-coated tablets, together with a leaflet.
Not all pack sizes may be marketed at one time.

Holder of Certificate of Registration
Macleods Pharmaceuticals SA (Pty) Ltd.
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext 12, Alberton.
Tel: +27 11 682 1169

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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 +27 11 682 1169.

MACLEODS

PM0063-02

Pasiëntinligtingsblad

SKEDULERINGSTATUS: S4

VCIDE® 50 FC, filmbedekte tablet
VCIDE® 200 FC, filmbedekte tablet
Vorikonasool
Bevat suiker (laktosemonohidraat).
Elke **VCIDE 50 FC**-tablet bevat 58,77 mg laktosemonohidraat en elke **VCIDE 200 FC**-tablet bevat 235,08 mg laktosemonohidraat.

Lees hierdie hele blad noukeurig deur voordat u begin om VCIDE te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, vra asseblief vir u dokter of u apteker.
- **VCIDE** is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat in hierdie blad is
1. Wat **VCIDE** is en waarvoor dit gebruik word
2. Wat u moet weet voordat u **VCIDE** drink
3. Hoe om **VCIDE** te drink
4. Moontlike newe-effekte
5. Hoe om **VCIDE** te bêre
6. Inhoud van die pak en ander inligting

1. Wat VCIDE is en waarvoor dit gebruik word
VCIDE is 'n antiswammiddel. Dit werk deur die swamme wat infeksies veroorsaak, dood te maak of die groei daarvan te stop.
VCIDE word gebruik vir die behandeling van pasiënte (volwassenes en kinders ouer as 2) met:
- indringende aspergillose ('n ernstige soort swaminfeksie as gevolg van *Aspergillus sp*).
- ernstige indringende *Candida* sp. infeksies (waaronder *C. krusei*).
- ernstige swaminfeksies veroorsaak deur *Scedosporium sp.* of *Fusarium sp.* (twee verskillende soorte swamme).

VCIDE kan ook gebruik word vir die voorkoming van swaminfeksies in pasiënte met 'n hoë risiko, byvoorbeeld ontvangers van beenmurgoorplantings, waar 'n ander antifungusmiddel nie gebruik kan word nie.
VCIDE moet slegs onder die toesig van 'n dokter gebruik word.

2. Wat u moet weet voordat u VCIDE drink
Moenie VCIDE drink nie:
- as u allergies (hipersensitief) vir vorikonasool of vir enige van die ander bestanddele (gelys in afdeling 6) van **VCIDE** is.
- as u die lang-QT-sindroom het ('n hartritmestoornis).
- as u lewerfunksie erg aangetas is.
- as u swanger is of borsvoed.

Dit is baie belangrik dat u vir u dokter of apteker sê as u enige ander medisyne gebruik of gebruik het, en selfs dié wat sonder voorskrif verkry word, of kruiemiddels. Daar is baie medisyne wat **nie** tydens die kursus van behandeling met **VCIDE** gedrink moet word nie:
- Terfenadien (vir allergie)
- Astemisool (vir allergie)
- Sisapried (vir maagprobleme)
- Pimosied (vir die behandeling van geestesongesteldheid)
- Kinidien (vir onreëlmatige hartklop)
- Rifampisien (om tuberkulose te behandel)
- Karbamasepien (om stuipe te behandel)
- Fenobarbitaal (vir erge slapeloosheid en stuipe)
- Ritonavir (vir MIV) teen dosisse van **400 mg** en meer, twee keer per dag
- Ergotalkaloïede (bv. ergotamien, dihidroërgotamien, vir migraine)
- Sirolimus (gebruik deur oorplantingspasiënte)
- Rifabutien (vir tuberkulose)
- Sint Janskruid ("St John's Wort") (kruieaanvulling)

Waarskuwings en voorsorgmaatreëls
Sê vir u dokter, apteker of gesondheidsorgverskaffer voordat u **VCIDE** gebruik as:
- u allergies vir ander medisyne van die asool-tipe is (dit is antifungusmiddels, byvoorbeeld flukonasool of ketokonasool. Vra vir u dokter of apteker as u onseker is).
- u aan 'n lewersiekte ly of ooit daaraan gely het. As u 'n lewersiekte het, kan u dokter 'n laer dosis van **VCIDE** voorskryf. U dokter moet ook u lewerfunksie monitor deur bloedtoetse te doen terwyl u met **VCIDE** behandel word.
- dit bekend is dat u kardiomiopatie (siek hartspier), onreëlmatige hartklop, stadige hartklop of 'n abnormaliteit van elektrokardiogram (EKG) genaamd 'lang QTc -sindroom' het (sien afdeling 2 "Moenie **VCIDE** drink nie").
- u elektrolietstoornisse soos lae kalium-, kalsium- of magnesiumvlakke het.
- u 'n niersiekte het. U dokter moet ook u nierfunksie monitor deur bloedtoetse te doen terwyl u met **VCIDE** behandel word.

U moet ook weet dat:
U moet sonlig en blootstelling aan die son vermy terwyl u behandel word. Dit is belangrik om vel wat aan die son blootgestel is, te bedek en om sonskerm met 'n hoë sonbeskermingsfaktor (SBF) te gebruik, aangesien 'n hoër sensitiwiteit van die vel vir die son se UV-strale kan voorkom. Hierdie voorsorgmaatreëls is ook op kinders van toepassing.
Sê dadelik vir u dokter as u die volgende ervaar terwyl u met **VCIDE** behandel word:
- sonbrand
- erge veluitslag of blase
- pyn in die skeletbene

As u velafwykings ontwikkel soos hierbo beskryf, kan u dokter u na 'n dermatoloog verwys, wat na konsultasie kan besluit of dit belangrik is dat u gereeld gesien moet word. Daar is 'n klein kans dat velkanker met langdurige gebruik van **VCIDE** kan ontwikkel.
VCIDE kan probleme met u oë en visie veroorsaak, waaronder dowwe sig en liggevoeligheid. U moet 'n sonbril dra om u oë teen helder lig te beskerm.
As u 'n orgaanoorplanting gehad het en **VCIDE** gekry het, kan u ontsteking en pyn in die skeletbene hê. Raadpleeg u dokter so gou as moontlik. Hy/sy sal besluit of u met die behandeling met **VCIDE** moet voortgaan en sal u soos nodig behandel.
Doeltreffende voorbehoeding moet deur vroue in die vrugbare ouderdom gebruik word.
Kinders
VCIDE word nie vir kinders van jonger as 2 jaar aanbeveel nie omdat daar onvoldoende data oor die veiligheid en effektiwiteit in hierdie ouderdomsgroep is.

Ander medisyne en VCIDE
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (dit sluit alle aanvullende en tradisionele medisyne in).
Sekere medisyne wat saam met **VCIDE** gebruik word, kan die werking van **VCIDE** beïnvloed, of **VCIDE** kan hulle werking beïnvloed.
VCIDE moet nie gedrink word nie *as u reeds enige van die middels op die volgende lys gebruik. Sê vir u dokter as u enige van die volgende gebruik:*
- Astemisool (vir allergie)
- Terfenadien (vir allergie)
- Sisapried (vir maagprobleme)
- Pimosied (vir die behandeling van geestesongesteldheid)
- Kinidien (vir onreëlmatige hartklop)
- Karbamasepien (om stuipe te behandel)
- Fenobarbitaal (vir erge slapeloosheid en stuipe)
- Efavirens (vir die behandeling van MIV) teen dosisse van 400 mg en meer as een keer per dag
- Ergotalkaloïede (bv. ergotamien, dihidroërgotamien, vir migraine)
- Rifampisien (om tuberkulose te behandel)
- Ritonavir (vir MIV) teen dosisse van **400 mg** en meer, twee keer per dag
- Rifabutien (vir tuberkulose)
- Sint Janskruid ("St John's Wort") (kruieaanvulling)
- Sirolimus (gebruik deur oorplantingspasiënte)

*Sê vir u dokter as u enige van die volgende middels gebruik, aangesien behandeling saam met **VCIDE**, indien moontlik, vermy moet word:*
- Ritonavir (vir MIV) teen dosisse van **100 mg** twee keer per dag
- Fenitoïen (vir die behandeling van epilepsie). As u reeds fenitoïen gebruik, moet die konsentrasie fenitoïen in u bloed tydens u behandeling met **VCIDE** gemonitor word en u dosis moet dalk aangepas word.

*Sê vir u dokter indien u enige van die volgende middels gebruik, aangesien dosisaanpassing of monitering nodig mag wees om te kyk of die medisyne en/of **VCIDE** steeds die gewensde uitwerking het:*
- Everolimus (vir die behandeling van gevorderde nierkanker en vir oorplantingspasiënte)
- Flukonasool (vir fungusinfeksies)
- Warfarien en ander antistolmiddels (bv. fenprokumoon, asenokumarol; om bloedstolling te vertraag)
- Bensodiasepiene (bv. midasolaam, triasolaam) (vir erge slapeloosheid en spanning)
- Siklosporien (gebruik deur oorplantingspasiënte)
- Takrolimus (gebruik deur oorplantingspasiënte)
- Oksikodoon en ander langwerkende opiate soos hidrokodoon (vir matige tot erge pyn)
- Metadoon (om heroïenverslawing te behandel)
- Nie-steroïed anti-inflammatoriese middels (bv. ibuprofeen, diklofenak) (vir pyn en inflammasie)
- Omeprasool (vir maagsere)
- Orale voorbehoedmiddels (as u **VCIDE** gebruik terwyl u orale voorbehoedmiddels drink, kan u newe-effekte soos naarheid en menstruele afwykings ervaar)
- Alfentaniel en fentaniel en ander kortwerkende opiate soos sufentaniel (pynstillers wat gebruik word vir chirurgiese prosedures)
- Statiene (bv. atorvastatien, simvastatien) (om cholesterolvlakke te verlaag)
- Sulfonielureums (bv. tolbutamied, glipisied en gliburied) (vir diabetes)
- Vinka-alkaloïede (bv. vinkristien en vinblastien) (vir kanker)
- Ander protease-remmers (byvoorbeeld sakinavir, amprenavir en nelfinavir)
- Nie-nukleosied trutranskriptaseremmers (bv. efavirens, delavirdien, nevirapien) (vir MIV) (sommige dosisse van efavirens kan NIE saam met **VCIDE** gedrink word nie)

Moenie met nuwe medisyne begin of dit gebruik voordat u dit met u dokter of apteker bespreek het nie. U dokter en apteker het meer inligting oor medisyne wat tydens die gebruik van **VCIDE** versigtig hanteer of vermy moet word.

Swangerskap en borsvoeding
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidsorgverskaffer asseblief om advies raadpleeg voordat u **VCIDE** drink.
Daar is nie voldoende inligting oor die gebruik van **VCIDE** deur swanger vroue nie. Studies met diere het 'n toksiese effek op die ontwikkelende fetus aangetoon. Die moontlike risiko vir mense is onbekend. **VCIDE** moet nie tydens swangerskap gebruik word nie.
U moet effektiewe voorbehoeding gebruik as u vrugbaar is. Skakel u dokter dadelik as u swanger raak terwyl u VCIDE drink.
Dit is nie bekend of **VCIDE** in borsmelk uitgeskei word nie. U moet nie u baba borsvoed as u **VCIDE** drink nie.

Motorbestuur en gebruik van masjinerie
VCIDE kan maak dat u dowwe visie het en duiselig voel (sien afdeling 4). As dit met u gebeur, moet u nie motor bestuur of gereedskap of masjinerie hanteer nie.

VCIDE bevat laktose
VCIDE bevat laktosemonohidraat ('n tipe suiker). As u dokter dus vir u gesê het dat u 'n onverdraagbaarheid teenoor sekere suikers het, moet u u dokter skakel voordat u hierdie medisyne drink.

3. Hoe om VCIDE te drink
Moenie medisyne wat vir u of u kind voorgeskryf is aan enigiemand anders gee nie.
Drink **VCIDE** altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
U dokter sal besluit watter dosis u vir u toestand moet kry en ook vir hoe lank u dit moet kry. Die dosis en duur van die behandeling sal afhang van hoe u liggaam en die infeksie op die behandeling reageer.
Afhangende van u reaksie op die behandeling, kan u dokter u dosis verhoog of verlaag.
Drink u tablet minstens een uur voor, of een uur na 'n maaltyd. Sluk die tablet heel met 'n bietjie water af.

Gebruik deur kinders en adolessente
Tablette moet slegs gegee word as die kind tablette kan sluk.
Die kind se dokter sal die dosis vir u kind bereken, gebaseer op sy/haar massa.
Hy/sy sal vir u sê hoe lank die behandeling met **VCIDE** sal duur.
Drink u tablet minstens een uur voor, of een uur na 'n maaltyd. Sluk die tablet heel met 'n bietjie water af.
Hou aan om **VCIDE** te drink totdat u dokter vir u sê om op te hou. Moenie die behandeling vroeg staak nie want u infeksie is dalk nie genees nie. Langtermynbehandeling kan nodig wees vir pasiënte met 'n verswakte immuunstelsel of diegene met moeilike infeksies om te voorkom dat die infeksie terugkeer.
Sê vir u dokter of apteker as u die indruk het dat die effek van **VCIDE** te sterk of te swak is.

As u meer VCIDE gedrink het as wat u moes
Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om VCIDE te drink
Moenie 'n dubbele dosis gebruik om vir vergete individuele dosisse op te maak nie.

As u ophou om VCIDE te drink
Dit is belangrik dat u u behandeling voltooi soos deur u dokter voorgeskryf.
Moenie ophou om **VCIDE** te drink omdat u beter voel nie. As u ophou om die medisyne te drink voordat die kursus voltooi is, kan die swam wat die siekte veroorsaak, weerstandig teen **VCIDE** raak en u siekte sal erger word.

4. Moontlike newe-effekte
VCIDE kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir **VCIDE** aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u enige newe-effekte ervaar terwyl u **VCIDE** drink, moet u u dokter, apteker of ander gesondheidsorgverskaffer om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om VCIDE te drink en u dokter dadelik daarvan sê.
- Ernstige allergiese reaksies, waaronder 'n skokreaksie. U kan swelling van die tong en/of keel hê, probleme met sluk, asemhalingsprobleme, swelling van die gesig, erge duiseligheid met baie vinnige hartklop en baie sweet.
- Allergiese velreaksies (soms erg), waaronder vinnige swelling (edeem) van die dermis, onderhuidse weefsel, slymvlies en submukosale weefsel, jeukerige of seer kolle van dik, rooi vel met silweragtige skubbe, irritasie van die vel en slymvliese, lewensbedreigende veltoestand wat veroorsaak dat groot dele van die epidermis, die buitenste laag van die vel, loskom van die onderliggende vellae.

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige reaksie op **VCIDE** gehad het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:
- Geelsug (geel verkleuring van die oë of vel, donker urien, boonste maagpyn), lewerversaking, galblaassiekte, galstene.
- Verswakking van breinfunksie wat 'n ernstige komplikasie van lewersiekte is.
- Ontsteking van die pankreas (buikpyn, koors, vinnige polsslag, naarheid, rillings).
- Erge diarree en naarheid met koors en swakheid. Dit is 'n ernstige toestand waarvoor u dringend behandeling nodig het.
- Hartritmestoornisse, waaronder 'n baie vinnige hartklop, baie stadige hartklop, geleidingsprobleme (soms lewensgevaarlik), floute.
- Dubbelvisie, ernstige toestande van die oë, waaronder pyn en ontsteking van die oë en ooglede, abnormale oogbeweging, beskadiging van die optiese senuwee wat tot gesigsgestremdheid lei, swelling van die optiese skyf.
- Versteuring van die bloedstollingstelsel (stolling in die bloedvate).
- Guillain-Barresindroom (die immuunstelsel van die liggaam val 'n deel van die perifere senustelsel aan, met spierswakheid wat in die voete en hande begin).
- Nierversaking, ontsteking in die niere, bloed in die urien, probleme met urinering, veranderinge in uitslae van nierfunksietoetse, proteïene in die urien.

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê vir u dokter as u enige van die volgende opmerk:
Gereelde newe-effekte
- Sinusitis (infeksie van die neusgange)
- Lae tellings van sommige soorte bloedselle, waaronder erge daling in rooi- (soms immuunverwant) en/of witbloedselle (soms met koors), min selle wat bloedplaatjies genoem word, wat die bloed help stol.
- U kry meer infeksies as gewoonlik. Dit kan vanweë 'n afname in die aantal witbloedselle wees. U dokter sal dit met 'n bloedtoets bevestig.
- Lae vlakke suiker, kalium of natrium in die bloed (u sal slegs seker wees dat u hierdie tekorte het as u vir bloedtoetse gaan). Sê vir u dokter as u spierkrampe het en swak voel
- Maklike of oormatige kneusing, oppervlakkige bloeding in die vel, onverwagte oormatige bloeding, veral as u ook medisyne soos warfarien gebruik wat bloed dun maak
- Depressie, probleme om aan die slaap te raak, angs, hallusinasies (valse persepsies)
- Slaperigheid, flouheid en/of duiseligheid
- Konvulsies (toevalle of rukkings), erge hoofpyn, verlies van koördinasie
- Tinteling of abnormale velsensasies, toename in spiertonus
- Bloeding in die oë
- Lae bloeddruk (u kan flou of duiselig voel)
- Inflammasie van 'n aar (flebitis, 'n toestand waarin die are naby die oppervlak van die liggaam geswel, sag en rooi word en bloedklonte kan ontwikkel)
- Naarheid (voel mislik), braking (bring op), diarree (los stoelgang), maagpyn, ontsteking van die lippe
- Hardlywigheid, slegte spysvertering
- Veluitslag, haarverlies
- Rugpyn
- Voel moeg en oor die algemeen swak

Minder gereelde newe-effekte
- Vergrote limfkliere (soms pynlik), versaking van beenmurg, meer eosinofiele
- Versteuring in die bloedstolstelsel
- Ooraktiewe skildklier. Sê vir u dokter as u spierswakheid, 'n vinnige hartklop en groter eetlus het
- Onderaktiewe skildklier (van die tekens kan gewigstoename, moegheid en depressie wees)
- Abnormale smaaksin
- Laer sensitiwiteit vir aanraking
- Abnormale breinfunksie, Parkinsonagtige simptome, senubesering wat gevoelloosheid tot gevolg het, pyn, tinteling of brandgevoel in die hande of voete
- Skielike gedragsveranderinge, probleme met denke of spraak
- Probleme met balans of koördinasie, swelling van die brein
- Oogrolversteuring waar die oë na bo kyk
- Gelui in die ore, duiseligheid, gehoorverlies
- Ontsteking van sekere inwendige organe - pankreas en duodenum, swelling en ontsteking van die tong
- Ontsteking van die dun weefsel wat die binnewand van die buik uitvoer en die buikorgane bedek
- Blaasagtige fotosensitiwiteit
- Sproete en gepigmenteerde kolle
- Gewrigs- en spierpyn in die bene en arms
- Griepagtige siekte
- Meer cholesterol in die bloed

Ander beduidende newe-effekte waarvan die frekwensie nie bekend is nie, maar wat onmiddellik by u dokter aangemeld moet word:
- velkanker
- ontsteking van die weefsel rondom skeletbene
- rooi, skubberige vlekke of ringvormige velletsels wat 'n simptoom kan wees van 'n outo-immuun siekte genaamd kutane lupuseritematose

Party newe-effekte soos tydelike bloed-, cholesterol-, nier- of lewerprobleme kan slegs opgespoor word as u dokter bloed- of urientoetse aanvra om u vordering te kontroleer.
Sonbrand of erge velreaksie na blootstelling aan lig of son is meer dikwels deur kinders ervaar. As u of u kind velafwykings ontwikkel soos hier bo beskryf, kan u dokter u na 'n dermatoloog verwys, wat na konsultasie kan besluit of dit belangrik is dat u of u kind gereeld gesien moet word. Hoër vlakke lewerensieme is ook meer dikwels in kinders waargeneem.
As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Praat met u dokter, apteker of verpleegkundige as u newe-effekte kry.
U kan newe-effekte ook by SAHPRA op hulle webwerf aanmeld:
https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van **VCIDE** te gee.

5. Hoe om VCIDE te bêre
Hou alle medisyne buite bereik van kinders.
Bêre in die oorspronklike verpakking by of onder 25 °C.
U moet dit nie na die vervaldatum op die etiket en karton gebruik nie.
Bottels: Gebruik binne 30 dae nadat dit vir die eerste keer oopgemaak is.
Gee alle ongebruikte medisyne terug aan u apteker. Ongebruikte medisyne moet nie in dreinering- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting
Wat VCIDE bevat
- Die aktiewe bestanddeel is vorikonasool.
  Elke **VCIDE 50 FC**-tablet bevat 50 mg vorikonasool en elke **VCIDE 200 FC**-tablet bevat 200 mg vorikonasool.
- Die ander bestanddele is vooraf geswelde mieliestysel, laktosemonohidraat, povidoon K30, natriumkruiskarmellose, kolloïdale watervrye silika en magnesiumstearaat. Die tabletbedekking Opadry II White OY-LS-28908, bevat titaandioksied (E171), laktosemonohidraat, hipromellose (E464) en makrogol/PEG (E1521).

Hoe VCIDE lyk en die inhoud van die pakkie
Filmbedekte tablette.
VCIDE 50 FC-tablette word aangebied as wit tot afwit ronde, bikonvekse filmbedekte tablette met kode V50 op die een kant.
VCIDE 200 FC-tablette word aangebied as wit tot afwit ovaalvormige, bikonvekse filmbedekte tablette met kode V200 op die een kant.
Die tablette is verpak in:
Kartonne met deursigtige stulpstroke van PVC/aluminiumfoelie met 2, 7, 10, 14, 20, 28, 30, 50, 56 of 100 filmbedekte tablette, saam met 'n voubiljet.
Kartonne met wit ondeursigtige HDPE-bottels, met kindbestande polipropileen-skroefdoppe en induksieseëlvoerings, met 30 filmbedekte tablette, saam met 'n voubiljet.
Dit kan wees dat nie al die pakgroottes op een slag bemark word nie.

Houer van die registrasiesertifikaat
Macleods Pharmaceuticals SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos)
Cussoniarylaan 1, Bassonia Rock, Uitbr.12, Alberton.
Tel: +27 11 682 1169

Hierdie blad is laas hersien in
20 April 2021

Registrasienommers
VCIDE 50 FC: 50/20.1.7/0786
VCIDE 200 FC: 50/20.1.7/0787

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 +27 11 682 1169

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Product:	267458_LEAFLET VCIDE (VORICO) TABS Macleods ZA
Code:	2834652/2
File:	3rd
Pharmacode:	9523
Material:	50gsm
Size Unfolded:	170x500
Size Folded:	170x33
Date:	21/5/25 9:28 AM
Operator:	A.C.

Colors:
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CUTTER
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Date: 21/05/2025

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Viltanioti str. 24, 145 64 K.Kifissia-Greece, Tel.: +30 210 2846800, +30 211 8807100 Fax: +30 210 2851207, www.paperpack.gr info@paperpack.gr