APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

VONDIP IV 200 mg powder for solution for infusion

Voriconazole

VONDIP IV 200 mg is sugar free.

Read all of this leaflet carefully before you are given VONDIP IV 200 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- VONDIP IV 200 mg 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 VONDIP IV 200 mg is and what it is used for

VONDIP IV 200 mg contains voriconazole, one of a group of medicines called triazole antifungal agents.

VONDIP IV 200 mg is an antifungal medicine. It works by killing or stopping the growth of the fungi that cause a wide variety of fungal infections and for the prevention of fungal infections in high risk bone marrow transplant recipients.

VONDIP IV 200 mg should only be used under the supervision of a doctor.

2. What you need to know before you are administered VONDIP IV 200 mg

VONDIP IV 200 mg should not be administered to you:

- if you are hypersensitive (allergic) to voriconazole or any of the other ingredients of VONDIP IV 200 mg (see section 6)
- if you have an abnormality of electrocardiogram (ECG) called ‘long QTc syndrome’
- if you suffer from serious liver problems
- if you are pregnant or breastfeeding (see Pregnancy and Breastfeeding).

The medicines in the following list must **NOT** be taken during your treatment with VONDIP IV 200 mg:

- cisapride (for stomach problems)
- pimozide (for treating mental illness)
- astemizole or terfenadine (to treat allergies)
- ivabradine (to treat heart failure)
- quinidine (for irregular heart beat)
- efavirenz (to treat HIV) in doses of 400 mg or more daily
- naloxegol (to treat constipation specifically caused by pain medicines, called opioids, e.g., morphine, oxycodone, fentanyl, tramadol, codeine)
- tolvaptan (to treat low blood sodium levels or to slow kidney function decline in patients with polycystic kidney disease)
- lurasidone (to treat symptoms of mental disorders)
- venetoclax (to treat patients with chronic lymphocytic leukaemia - CLL)
- ritonavir (to treat HIV) in doses of 400 mg or more twice daily
- carbamazepine (to treat severe seizures)
- phenobarbitone (for severe insomnia and seizures)
- rifampicin (to treat tuberculosis)
- rifabutin (to treat tuberculosis)
- ergot alkaloids (e.g. ergotamine, dihydroergotamine; for migraine)
- sirolimus and everolismus (given to transplant patients)
- St John’s Wort (herbal supplement).

VONDIP IV 200 mg is not recommended for use in children younger than 2 years of age.

Warnings and precautions

Take special care with VONDIP IV 200 mg:

Tell your doctor or healthcare professional before being given the injection:

- you are using contraceptives
- you have had an allergic reaction to other antifungal medicines
- if you are known to have cardiomyopathy, irregular heartbeat, slow heart rate or an abnormality of electrocardiogram (ECG) called ‘long QTc syndrome’
- you are suffering from or have ever suffered from liver disease. If you have liver disease your doctor may prescribe a lower dose of VONDIP IV 200 mg. Your doctor should also monitor your liver function while you are treated with VONDIP IV 200 mg, by testing your blood
- you are suffering from or have ever suffered from kidney disease. Your doctor should monitor your renal function while you are being treated with VONDIP IV 200 mg by doing blood tests.

While being treated with VONDIP IV 200 mg:

- at the start of treatment, you will feel faint, feverish, flushed, nausea, sweaty, tight chest and have difficulty breathing
- tell your doctor immediately if you develop a severe skin rash or blisters

- tell your doctor immediately if you develop bone pain
- avoid sunlight while being treated with VONDIP IV200 mg, as an increased sensitivity of skin to the sun's UV rays can occur.

  It is important to cover areas of skin exposed to the sun and use sunscreen with a high sun protection factor (SPF)
- if you develop eye problems
- if you develop pancreatitis (inflammation of the pancreas, which causes severe pain in the abdomen and back)
- your doctor should monitor the function of your liver and kidneys by doing blood tests.

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 VONDIP IV 200 mg.

Tell your doctor if you develop signs of adrenal insufficiency where the adrenal glands do not produce adequate amounts of certain steroid hormones, such as cortisol, which may lead to symptoms including chronic, or long lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain.

Tell your doctor if you develop signs of Cushing's syndrome where the body produces too much of the hormone cortisol, leading to symptoms including weight gain, fatty hump between the shoulders, a rounded face, darkening of the skin on the stomach, thighs breasts, and arms, thinning skin, bruising easily, high blood sugar, excessive hair growth, excessive sweating.

Children

VONDIP IV 200 mg should not be given to children younger than 2 years of age.

Other medicines and VONDIP IV 200 mg

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines, when taken at the same time as VONDIP IV 200 mg, may affect the way VONDIP IV 200 mg works or VONDIP IV 200 mg may affect the way they work.

Tell your doctor if you are taking any of the medicines listed in section 2 above (**VONDIP IV 200 mg should not be administered**).

Tell your doctor if you are taking the following medicine, as treatment with VONDIP IV 200 mg at the same time should be avoided if possible:

- everolimus (used in organ transplant patients and used to treat kidney cancer)
- ritonavir (used for treating HIV) in doses of 100 mg twice daily
- phenytoin (used to treat epilepsy).

Tell your doctor if you are taking any of the following medicines, as a dose adjustment or monitoring may be required to check that they are still having the desired effect:

- methadone (to treat heroin addiction)
- alfentanil, fentanyl and other short-acting opiates (painkillers used for surgical procedures)
- oxycodone and other long-acting opiates (e.g. hydrocodone) (for moderate to severe pain)
- ciclosporin and tacrolimus (used in organ transplant patients)
- warfarin and other anti-coagulants (including but not limited to, phenprocoumon, acenocoumarol, used to slow down clotting of the blood)
- sulphonylureas e.g. tolbutamide, glipizide, glyburide (for diabetes)
- statins e.g. lovastatin (to lower cholesterol)
- benzodiazepines e.g. midazolam, triazolam, alprazolam (for severe insomnia and stress)
- vinca alkaloids e.g. vincristine, vinblastine (to treat cancer)
- Non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen, diclofenac (to treat pain and inflammation)
- omeprazole (to treat ulcers)
- oral contraceptives e.g. norethisterone and ethinylestradiol

- indinavir and other HIV protease inhibitors e.g. amprenavir, nelfinavir, saquinavir (to treat HIV)
- non-nucleoside reverse transcriptase inhibitors e.g. efavirenz, delavirdine, nevirapine (to treat HIV). Some doses of efavirenz can NOT be taken at the same time as VONDIP IV (see **VONDIP IV 200 mg should not be administered**)
- fluconazole (for fungal infections)
- letermovir (used for preventing cytomegalovirus (CMV) disease after bone marrow transplant)
- flucloxacillin (antibiotic used against bacterial infections)
- glasdegib (used to treat myelogenous leukaemia - a type of blood and bone marrow cancer that spreads quickly)
- tyrosine kinase inhibitors (e.g., axitinib, bosutinib, cabozantinib, ceritinib, cobimetinib, dabrafenib, dasatinib, nilotinib, sunitinib, ibrutinib, ribociclib) (used for treating cancer)
- ivacaftor (used to treat cystic fibrosis)
- tretinoin (used to treat leukaemia).

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using VONDIP IV 200 mg.

You should not be administered VONDIP IV 200 mg if you are pregnant or breastfeeding your baby (see VONDIP IV 200 mg should not be administered).

Effective contraception must be used by women of child-bearing age.

Driving and using machines

VONDIP IV 200 mg has moderate influence on the ability to drive and use machines.

VONDIP IV 200 mg may cause blurred vision or uncomfortable sensitivity to light. Whilst affected, do not drive or use any tools or machines. Tell your doctor if you experience any of these effects.

It is not always possible to predict to what extent VONDIP IV 200 mg 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 VONDIP IV 200 mg affects them.

VONDIP IV 200 mg contains sodium and cyclodextrin

Each vial contains 88,74 mg of sodium. This should be taken into consideration if you are on a strictly controlled salt diet.

Each vial contains cyclodextrin. If you have a kidney disease, talk to your doctor before you receive VONDIP IV 200 mg.

3. How to use VONDIP IV 200 mg

You will not be expected to give yourself VONDIP IV 200 mg. It will be given to you by a person who is qualified to do so.

VONDIP IV 200 mg will be given to you by intravenous infusion (injected into a vein) over a period of 1 to 2 hours.

Your doctor will prescribe the appropriate dose according to your condition.

Children:

Children aged between 12 and 16 years of age should be dosed as adults.

Your doctor will tell you how long your treatment with VONDIP IV 200 mg will last.

If you have the impression that the effect of VONDIP IV 200 mg is too strong or too weak, tell your doctor or pharmacist.

If you are administered more VONDIP IV 200 mg than you should

Since a healthcare professional will administer VONDIP IV 200 mg, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

If you forget to use VONDIP IV 200 mg

Since a healthcare professional will administer VONDIP IV 200 mg, it is unlikely that the dose will be missed.

If you stop using VONDIP IV 200 mg

When VONDIP IV 200 mg treatment is stopped by your doctor you should not experience any effects. However, if you were taking medicines containing ciclosporin or tacrolimus you must mention this to your doctor, as the dose will need to be adjusted.

4. Possible side effects

VONDIP IV 200 mg can have side effects.

Not all side effects reported for VONDIP IV 200 mg are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using VONDIP IV 200 mg, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using VONDIP IV 200 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching

- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VONDIP IV 200 mg. 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:

- sepsis (blood poisoning). Symptoms include fast heart rate, fever or chills, fast breathing
- jaundice, severe liver problems
- severe skin rashes (blisters, peeling, raw areas), red-purple rash that spreads and forms blisters
- heart rhythm problems including very fast heartbeat and very slow heartbeat
- difficulty breathing due to fluid in your lungs and other problems with breathing, chest pain.

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:

- flu-like symptoms, inflammation of the sinuses
- anaemia (feeling week or dizzy) and other blood cell changes which your doctor will detect by taking a blood test

- blood tests showing a decrease in potassium or sodium levels (causing irregular heartbeat, confusion, seizures, fatigue unconsciousness) or a decrease in blood sugar levels (causing heart palpitations, fatigue, pale skin, shakiness, sweating, hunger, irritability)
- agitation, anxiety, confusion, depression, hallucinations (hearing or seeing things which are not there), problems sleeping
- dizziness, headache, convulsions (fits), tingling or burning in the hands or feet (pins and needles), muscle problems (arms or legs are difficult to move), trembling
- blurred vision, changes to the colours you see, sensitivity of your eyes to the light, eye bleeding and other problems with your sight. These side effects are mild, fully reversible and normally resolve themselves within an hour
- low blood pressure, inflammation of a vein (which may be associated with the formation of a blood clot)
- heartburn, piles, abdominal distension (bloating), stomach pains, swelling of the lips, diarrhoea, feeling or being sick, indigestion, constipation, swollen gums
- changes in liver function (detected by blood tests)
- hair loss, redness or purple discolouration of the skin, swelling of the face, sunburn or severe skin reaction following exposure to light or sun, itchiness, rash, widespread blistering rash and skin peeling
- back pain

- kidney failure, blood in the urine, changes in kidney function, decreased creatinine (detected by blood tests)
- feeling weak or lacking strength, chest pain, chills, fever, inflammation at the injection site, swelling of the extremities.

Less frequent side effects:

- swelling or inflammation of the large intestine (colon) due to infection
- blood tests showing a severe decrease in number of white or red blood cells, small purplish or red spots, blood clots, increase in a type of white blood cell which may be associated with allergic reaction, disorder of blood clotting system, enlarged lymph nodes
- overactive thyroid (symptoms include irritability, fast heartbeat, increased sweating, weight loss)
- underactive thyroid (symptoms include weight gain, extreme tiredness and depression)
- blood tests showing increased cholesterol
- sleepiness during infusion of VONDIP IV 200 mg, problems with co-ordination, swelling of the brain, abnormal brain function, due to liver not functioning Parkinson-like symptoms (continuous spasms, muscle contractions, irregular jerky movements and slow movements), nerve injury resulting in weakness, numbness or pain (usually in hands or feet), abnormal eye movement, abnormal sense of taste

- inflammation of the eyes and eyelid, clouding of the cornea which affects sight, double vision, damage to the eye nerves, swelling of the optic (eye) nerve, which results in problems seeing, prolonged involuntary upward gaze of the eyes
- problems hearing, ringing in the ears, sensation of spinning when standing still
- diagnosed with an infection of the lymphatic system
- inflammation of the upper small intestine, problems with the pancreas, swollen tongue, peritonitis (inflammation of the lining of the abdominal cavity)
- inflammation of the gallbladder, gallstones, enlarged liver, hepatitis (inflammation of the liver), loss of consciousness due to liver failure
- skin rashes, swelling or inflammation of the skin, hives, skin redness and irritation, freckles and pigmented spots, eczema, psoriasis (scaly, itchy, dry patches of skin)
- arthritis (swollen or painful joints)
- kidney problems (damage to the kidney, proteins in the urine, inflammation of the kidney)
- blood chemistry changes (increased blood urea, increased blood cholesterol).

The following side effects have been reported but the frequency for them to occur is not known:

- skin cancer
- prominent rash on the cheeks and nose (“butterfly rash”), freckles
- inflammation, tenderness and swelling of the bones.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of VONDIP IV 200 mg. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store VONDIP IV 200 mg

Store all medicines out of reach of children.

Store at or below 25 °C.

Reconstitution of the vial must take place under aseptic conditions for microbial control.

After reconstitution with 19 mL of Water for Injections, the reconstituted solution should be used immediately. If the reconstituted solution is not used immediately, the reconstituted solution will remain suitable for its intended use up to 72 hours, store at 2 - 8 °C (in a refrigerator).

Do not freeze.

Protect from light. Keep the vial in the carton until required for use.

Do not use after the expiry date stated on the carton.

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 VONDIP IV 200 mg contains

The active substance is voriconazole.

Each vial contains 200 mg voriconazole.

The other ingredients are

Hydroxypropyl beta cyclodextrine, hydrochloric acid concentrated (for pH adjustment), sodium chloride.

What VONDIP IV 200 mg looks like and contents of the pack

White to off-white lyophilized powder.

After reconstitution with 19 mL of Water for Injections:

A clear, colourless solution.

Clear Type I glass vial (25 mL) sealed with a grey rubber stopper and red aluminium cap with red plastic sub-cap seal. Each vial is an outer carton.

Holder of Certificate of Registration

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