

SCHEDULING STATUS **S4**

VICOMYL 200 mg IV Powder for Solution for Infusion

Voriconazole 200 mg

Sugar free

Read all of this leaflet carefully before you start receiving

VICOMYL 200 MG IV

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

What is in this leaflet

1. What VICOMYL 200 MG IV is and what it is used for
2. What you need to know before you receive VICOMYL 200 MG IV
3. How to receive VICOMYL 200 MG IV
4. Possible side effects
5. How to store VICOMYL 200 MG IV
6. Contents of the pack and other information

1. What VICOMYL 200 MG IV is and what it is used for

VICOMYL 200 MG IV contains voriconazole.

VICOMYL 200 MG IV is an antifungal medicine. It works by killing or stopping the growth of the fungi that cause infections.

VICOMYL 200 MG IV is used for the treatment of patients (adults and children over the age of 2) with:

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- Invasive aspergillosis (a type of fungal infection due to a fungus named *Aspergillus sp.*).
- Candidaemia (another type of fungal infection due to a fungus named *Candida sp.*) in non-neutropenic patients (patients without abnormally low white blood cells count).
- Serious invasive *Candida sp.* infections when the fungus is resistant to fluconazole (another antifungal medicine). Serious fungal infections caused by fungi named *Scedosporium sp.* or *Fusarium sp.* (two different species of fungi).
- VICOMYL 200 MG IV is also used in the prevention of fungal infections in high-risk patients, e.g. bone marrow transplant recipients or relapsed leukaemia patients with worsening, possibly life-threatening, fungal infections.

2. What you need to know before you receive VICOMYL 200

MG IV

Do not receive VICOMYL 200 MG IV:

- if you are allergic (hypersensitive) to voriconazole or any other ingredients of VICOMYL 200 MG IV (listed in section 6);
- if you have had an allergic reaction to other azoles;
- if you are suffering from or have ever suffered from liver disease;
- If you have liver disease, your doctor may prescribe a lower dose of VICOMYL 200 MG IV;
- Your doctor should also monitor your liver function while you are being treated with VICOMYL 200 MG IV by doing blood tests;
- if you are pregnant or breastfeeding;
- if you have an illness called long QT syndrome;

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- if you are taking terfenadine (a medicine used for allergy);
- if you are taking astemizole (a medicine used for allergy);
- if you are taking cisapride (a medicine used for stomach problems);
- if you are taking pimozide (a medicine used for treating mental illness);
- if you are taking quinidine (a medicine used for irregular heart beat);
- if you are taking rifampicin (a medicine used for treating tuberculosis);
- if you are taking efavirenz (a medicine used for treating HIV) in doses of 400 mg and above once daily;
- if you are taking carbamazepine (a medicine used to treat seizures);
- if you are taking phenobarbital (a medicine used for severe insomnia and seizures);
- if you are taking ergot alkaloids (e.g., ergotamine, dihydroergotamine; medicines used for migraine);
- if you are taking ritonavir (a medicine used for treating HIV) in doses of 400mg and more twice daily;
- if you are taking St. John's Wort (herbal supplement);
- if you are taking rifabutin (an antibiotic used to treat tuberculosis and prevent and treat *Mycobacterium avium* complex);
- if you are taking sirolimus (used in transplant patients);
- if you are taking naloxegol (used to treat constipation specifically caused by pain medicines, called opioids, e.g., morphine, oxycodone, fentanyl, tramadol, codeine);
- if you are taking tolvaptan (used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline in patients with polycystic kidney disease);
- if you are taking lurasidone (used to treat depression);

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- if you are taking venetoclax (used to treat patients with chronic lymphocytic leukaemia - CLL).

VICOMYL 200 MG IV cannot be used by patients who

- are pregnant or breastfeeding;
- have 'long QT syndrome' (an abnormality of the electrocardiogram (ECG));
- have severe impairment of hepatic (liver) function.

Warnings and precautions

Tell your doctor or healthcare provider before being given VICOMYL 200

MG IV:

- if you are known to have cardiomyopathy, irregular heartbeat, slow heart rate or an abnormality of electrocardiogram (ECG) called 'long QTc syndrome' (see section '*Do not receive VICOMYL 200 MG IV*').
- if you are suffering from or have ever suffered from liver disease. If you have liver disease, your doctor may prescribe a lower dose of VICOMYL 200 MG IV. Your doctor should also monitor your liver function while you are being treated with VICOMYL 200 MG IV by doing blood tests.

You should avoid any sunlight and sun exposure while being treated. It is important to cover sun exposed areas of skin and use a 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 VICOMYL 200 MG IV:

Tell your doctor immediately if you develop:

- sunburn
- severe skin rash or blisters

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- 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 VICOMYL 200 MG IV.

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 such as: chronic, or long-lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain, please tell your doctor.

Tell your doctor if you develop signs of 'Cushing's syndrome' where the body produces too much of the hormone cortisol which may lead to symptoms such as 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 or excessive sweating, please tell your doctor.

Your doctor should monitor the function of your liver and kidneys by doing blood tests.

Children and adolescents

VICOMYL 200 MG IV should not be given to children younger than 2 years of age.

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Other medicines and VICOMYL 200 MG IV

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 VICOMYL 200 MG IV, may affect the way VICOMYL 200 MG IV works or VICOMYL 200 MG IV may affect the way they work.

Medicines in the following list **must not be taken** during your course of VICOMYL 200 MG IV treatment (see '*Do not receive VICOMYL 200 MG IV*')

- Terfenadine (a medicine used for allergy)
- Astemizole (a medicine used for allergy)
- Cisapride (a medicine used for stomach problems)
- Pimozide (a medicine used for treating mental illness)
- Quinidine (a medicine used for irregular heartbeat)
- Rifampicin (a medicine used for treating tuberculosis)
- Rifabutin (used for treating tuberculosis)
- Efavirenz (a medicine used for treating HIV) in doses of 400 mg and above once daily
- Carbamazepine (a medicine used to treat seizures)
- Phenobarbital (a medicine used for severe insomnia and seizures)
- Ergot alkaloids (e.g. ergotamine, dihydroergotamine; medicines used for migraine)
- Sirolimus (a medicine used in transplant patients)
- Ritonavir (a medicine used for treating HIV) in doses of 400mg and more twice daily
- St. John's Wort (herbal supplement)
- Naloxegol (used to treat constipation specifically caused by pain medicines,



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called opioids, e.g., morphine, oxycodone, fentanyl, tramadol, codeine)

- Tolvaptan (used to treat hyponatremia (low levels of sodium in your blood) or to slow kidney function decline in patients with polycystic kidney disease)
- Lurasidone (used to treat depression)
- Venetoclax (used to treat patients with chronic lymphocytic leukaemia - CLL)

Tell your doctor if you are taking the following medicines, as treatment with VICOMYL 200 MG IV at the same time should be avoided if possible:

- Ritonavir (a medicine used for treating HIV) in doses of 100 mg twice daily.
- Glasdegib (used for treating cancer) – if you need to use both medicines your doctor will monitor your heart rhythm frequently.

Tell your doctor if you are taking either of the following medicines, as treatment with VICOMYL 200 MG IV at the same time should be avoided if possible, and a dose adjustment of voriconazole may be required:

- Phenytoin (a medicine 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 VICOMYL 200 MG IV and your dose may be adjusted.

Tell your doctor if you are taking on long-term corticosteroids e.g. prednisolone, including inhaled corticosteroids e.g. budesonide and intranasal corticosteroids.

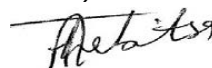
Tell your doctor if you are taking either of the following medicines, as treatment with VICOMYL 200 MG IV at the same time should be avoided if possible, and a dose adjustment or monitoring of VICOMYL 200 MG IV may be required:

- Warfarin and other anticoagulants (e.g. phenprocoumon, acenocoumarol;

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medicines used to slow down clotting of the blood)

- Ciclosporin (a medicine used in transplant patients)
- Tacrolimus (a medicine used in transplant patients)
- Sulfonylureas (e.g. tolbutamide, glipizide and glyburide) (medicines used for diabetes)
- Statins (e.g. atorvastatin, simvastatin) (medicines used for lowering cholesterol)
- Benzodiazepines (e.g. midazolam, triazolam) (medicines used for severe insomnia and stress)
- Omeprazole (a medicine used for treating ulcers)
- Oral contraceptives (if you take VICOMYL 200 MG IV whilst using oral contraceptives, you may get side effects such as nausea and menstrual disorders)
- Vinca alkaloids (e.g. vincristine and vinblastine) (medicines used for used in treating cancer)
- Indinavir and other HIV protease inhibitors (medicines used for used for treating HIV)
- Non-nucleoside reverse transcriptase inhibitors (e.g. efavirenz, delavirdine, nevirapine) (medicines used for treating HIV) (some doses of efavirenz CANNOT be taken at the same time as VICOMYL 200 MG IV).
- Methadone (a medicine used to treat heroin addiction)
- Alfentanil and fentanyl and other short-acting opiates such as sufentanil (painkillers used for surgical procedures)
- Oxycodone and other long-acting opiates such as hydrocodone (medicines used for used for moderate to severe pain)
- Non-steroidal anti-inflammatory drugs (e.g. ibuprofen, diclofenac) (medicines used for treating pain and inflammation)



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- Fluconazole (a medicine used for fungal infections)
- Everolimus (a medicine used for treating advanced kidney cancer and in transplant patients)
- Flucloxacillin (an antibiotic used against bacterial infections)
- Tyrosine kinase inhibitors (e.g. axitinib, bosutinib, cabozantinib, ceritinib, cobimetinib, dabrafenib, dasatinib, nilotinib, sunitinib, ibrutinib, ribociclib) (used for treating cancer)
- Tretinoin (used to treat leukaemia)
- Letermovir (used for preventing cytomegalovirus (CMV) disease after bone marrow transplant)
- Ivacaftor (used to treat cystic fibrosis)
- Corticosteroids, including inhaled corticosteroids and intranasal corticosteroids, e.g., prednisolone, budesonide (used to reduce inflammation)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby think you may be pregnant or are planning to get pregnant, tell your doctor, pharmacist or other healthcare professional for advice before receiving VICOMYL 200 MG IV.

Women of child-bearing potential

Effective contraception must be used in women of childbearing potential.

Pregnancy

VICOMYL 200 MG IV must not be given during pregnancy.

Contact your doctor immediately if you become pregnant while receiving treatment VICOMYL 200 MG IV.

Breastfeeding

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You should not breastfeed while you are receiving treatment with VICOMYL 200 MG IV.

Driving and using machines

VICOMYL 200 MG IV may cause blurring of vision or uncomfortable sensitivity to light. While affected, do not drive or operate any tools or machines. Contact your doctor if you experience this.

VICOMYL 200 MG IV contains sodium and cyclodextrin

VICOMYL 200 MG IV is considered high in sodium (222 mg/vial). This should be particularly taken into account for those on a low salt diet.

VICOMYL 200 MG IV also contains cyclodextrin (2978 mg/vial), which may accumulate in patients with moderate to severe kidney problems (renal dysfunction).

3. How VICOMYL 200 MG IV will be administered to you

You will not be expected to give yourself VICOMYL 200 MG IV. It will be given to you by a person qualified to do so. VICOMYL 200 MG IV powder for solution for infusion will be reconstituted and diluted to the correct concentration by your healthcare professional before it is given to you. It will be given to you by intravenous infusion

(into a vein in your arm with a needle) at a maximum rate of 3 mg/kg per hour over 1 to 2 hours.

Your doctor will determine your dose depending on your weight and the type of infection you have.

VICOMYL 200 MG IV will be administered by healthcare professionals as prescribed by the doctor.

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VICOMYL 200 MG IV for prevention of fungal infections, your doctor may stop giving VICOMYL 200 MG IV if you or your child develop treatment-related side effects.

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

If you receive more VICOMYL 200 MG IV than you should:

Since a healthcare provider will administer VICOMYL 200 MG IV, he / she will control the dosage. However, in the events of overdosage your doctor will manage the overdosage.

If you missed a dose of VICOMYL 200 MG IV:

Since a healthcare provider will administer VICOMYL 200 MG IV, it is unlikely that a dose will be missed. However, tell your doctor or nurse if you think that a dose has been forgotten.

Effects when treatment with VICOMYL 200 MG IV is stopped

- VICOMYL 200 MG IV treatment will continue for as long as your doctor advises, however duration of treatment with VICOMYL 200 MG IV should be no more than 6 months.
- Patients with a weakened immune system or those with difficult infections may require long-term treatment to prevent the infection from returning.
- You may be switched from the intravenous infusion to tablets once your condition improves.
- When VICOMYL 200 MG IV treatment is stopped by your doctor you should

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not experience any effects.

- If you have any further questions on the use of this medicine, ask your doctor, pharmacist or other healthcare professional.

4. Possible side effects

VICOMYL 200 MG IV can have side effects.

Not all side effects reported for VICOMYL 200 MG IV are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving VICOMYL 200 MG IV, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, tell your doctor or nurse immediately to stop administering VICOMYL 200 MG IV:

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- serious breathing difficulties;
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all very serious side effects. If you have them, you may have had a serious reaction to VICOMYL 200 MG IV. You may need urgent medical attention or treatment.

Tell your doctor or nurse immediately if you notice any of the following while receiving VICOMYL 200 MG IV:

- heart rhythm problems including very fast heartbeat, very slow heartbeat, fainting;

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- low blood pressure, inflammation of a vein (which may be associated with the formation of a blood clot);
- very fast heart rate or skipped heartbeats, sometimes with erratic electrical impulses;
- abnormal electrocardiogram (ECG);
- heart rhythm or conduction problems (sometimes life threatening);
- pancreatitis, inflammation of the pancreas.

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:

- visual impairment (change in vision including blurred vision, visual colour alterations, abnormal intolerance to visual perception of light, colour blindness, eye disorder, halo vision, night blindness, swinging vision, seeing sparks, visual aura, visual acuity reduced, visual brightness, loss of part of the usual field of vision, spots before the eyes),
- fever, rash,
- nausea, vomiting, diarrhoea,
- headache,
- swelling of the extremities,
- stomach pains,
- breathing difficulties,
- elevated liver enzymes,
- inflammation of the sinuses, inflammation of the gums, chills, weakness,
- 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,

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- low blood sugar, low blood potassium, low sodium in the blood,
- anxiety, depression, confusion, agitation, inability to sleep, hallucinations,
- seizures, tremors or uncontrolled muscle movements, tingling or abnormal skin sensations, increase in muscle tone, sleepiness, dizziness,
- bleeding in the eye,
- constipation, indigestion, inflammation of the lips,
- skin rashes which may lead to severe blistering and peeling of the skin characterized by a flat, red area on the skin that is covered with small confluent bumps, redness of the skin,
- itchiness,
- hair loss,
- back pain,
- kidney failure, blood in the urine, changes in kidney function tests.

Less frequent side effects:

- flu-like symptoms, irritation and inflammation of the gastrointestinal tract, inflammation of the gastrointestinal tract causing antibiotic associated diarrhoea, inflammation of the lymphatic vessels,
- inflammation of the thin tissue that lines the inner wall of the abdomen and covers the abdominal organ,
- enlarged lymph glands (sometimes painful), failure of blood marrow, increased eosinophil,
- depressed function of the adrenal gland, underactive thyroid gland,
- abnormal brain function, Parkinson-like symptoms, nerve injury resulting in numbness, pain, tingling or burning in the hands or feet,
- problems with balance or coordination,
- swelling of the brain,



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- 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,
- decreased sensitivity to touch,
- abnormal sense of taste,
- hearing difficulties, ringing in the ears, vertigo,
- inflammation of certain internal organs- pancreas and duodenum, swelling and inflammation of the tongue,
- enlarged liver, liver failure, gallbladder disease, gallstones,
- joint inflammation, inflammation of the veins under the skin (which may be associated with the formation of a blood clot),
- inflammation of the kidney, proteins in the urine, damage to the kidney,
- blood cholesterol increased, blood urea increased,
- allergic skin reactions (sometimes severe), including life-threatening skin condition that causes painful blisters and sores of the skin and mucous membranes, especially in the mouth, inflammation of the skin, hives, sunburn or severe skin reaction following exposure to light or sun, skin redness and irritation, red or purple discoloration of the skin which may be caused by low platelet count, eczema,
- infusion site reaction,
- allergic reaction or exaggerated immune response,
- overactive thyroid gland,
- deterioration of brain function that is a serious complication of liver disease,
- loss of most fibres in the optic nerve, clouding of the cornea, involuntary movement of the eye,
- bullous photosensitivity,
- a disorder in which the body's immune system attacks part of the peripheral

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nervous system,

- disorder of blood clotting system,
- 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,
- small dry scaly skin patches, sometimes thick with spikes or 'horns',
- infusion site reaction.

Side effects with frequency not known:

- freckles and pigmented spots,
- 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.

As VICOMYL 200 MG IV has been known to affect the liver and the kidney, your doctor should monitor the function of your liver and kidney by doing blood tests. Please advise your doctor if you have any stomach pains or if your stools have a different consistency.

There have been reports of skin cancer in patients treated with VICOMYL 200 MG IV for long periods of time.

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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.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions 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 VICOMYL 200 MG IV.

5.How to store VICOMYL 200 MG IV

- Store all medicines out of reach of children.
- Powder for solution for infusion: Store at or below 25 °C.
- Reconstituted concentrate: Store at 2 °C - 8 °C for up to 24 hours (in a refrigerator).
- Reconstituted VICOMYL needs to be diluted with a compatible infusion solution first before it is infused.

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- Do not use after the expiry date stated on the carton label.
- 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 VICOMYL 200 MG IV contains

The active substance is voriconazole.

Each VICOMYL 200 MG IV 200 mg vial contains 200 mg voriconazole.

When reconstituted as directed, each ml contains 10 mg voriconazole.

The other ingredients are:

Sulphobutylether beta cyclodextrin sodium (SBECD), which contains:

- Sodium 222 mg
- Cyclodextrin 2978 mg

What VICOMYL 200 MG IV looks like and contents of the pack

VICOMYL 200 MG IV powder for solution for infusion is a white lyophilised powder or cake filled in flint vial with rubber stopper and aluminium seal.

Contents of the pack:

VICOMYL 200 MG IV powder for solution for infusion is available as a single use 30 ml Type I tubular flint glass vial with bromobutyl lyo stopper, flip-off aluminium seal.

Pack size: 1 vial

Holder of Certificate of Registration

VIATRIS SOUTH AFRICA (PTY) LTD

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4 Brewery Street

Isando

Johannesburg, 1609

Republic of South Africa

This leaflet was last revised in

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Registration numbers

52/20.1.1/0993

Access to the corresponding Professional Information

To follow

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