Applicant/PHRC: ***Hetero Drugs South Africa (Pty) Ltd***

Product proprietary name: ***VAGLOR***

Dosage form and strength: ***Powder for oral solution and each mL of constituted oral solution contains valganciclovir free base 50 mg equivalent to 55,15 mg of valganciclovir hydrochloride***

FINAL PATIENT INFORMATION LEAFLET FOR VAGLOR

SCHEDULING STATUS

S4

VAGLOR powder for oral solution

Valganciclovir hydrochloride

Preservative: Sodium benzoate 1 mg/mL

Contains sugar (57,150 mg mannitol per mL)

Contains sweetener (0,300 mg saccharin sodium per mL)

Read all of this leaflet carefully before you start taking VAGLOR

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

VAGLOR belongs to a group of medicines that work to prevent the growth of viruses.

VAGLOR is used:

- for the treatment of cytomegalovirus (CMV)-infections of the retina of the eye in adult patients with acquired immunodeficiency syndrome (AIDS). CMV-infection of the retina of the eye can cause vision problems and even blindness.
- to prevent CMV-infections in adults and children who are not infected with CMV and who have received an organ transplant from somebody who was infected by CMV.

After taking **VAGLOR**, the valganciclovir is quickly changed in your body to release ganciclovir, which is the active medicine. Ganciclovir prevents the growth and the increase in numbers of a virus called cytomegalovirus (CMV).

2. What you need to know before you take VAGLOR

Do not take VAGLOR:

- If you are hypersensitive (allergic) to valganciclovir, ganciclovir, aciclovir, valaciclovir or any of the other ingredients of VAGLOR **(**listed in section 6).
- If you are breastfeeding.
- If you have ever had an allergic reaction to acyclovir or valaciclovir (used to treat viral infections caused by herpes simplex including cold sores).

Warnings and precautions

Take special care with VAGLOR:

- If you have low numbers of white blood cells, red blood cells or platelets (small cells involved in blood clotting) in your blood. Your doctor will carry out blood tests before you start taking VAGLOR and more tests will be done while you are taking the powder for oral solution.

- If you are having radiotherapy or haemodialysis. If your doctor decides to give you VAGLOR, your blood will need to be checked frequently.
- If you have a problem with your kidneys. Your doctor may need to prescribe a reduced dose for you and may need to check your blood frequently during treatment.
- If you are currently taking ganciclovir capsules and your doctor wants you to switch to VAGLOR powder for oral solution. It is important that you do not take more than the prescribed dose by your doctor or you could risk an overdose.
- VAGLOR can cause potential birth defects. If you are a woman, and able to get pregnant you should use effective contraception during your treatment and for 30 days after treatment has ended. Men must be advised to use a condom during treatment, and for 90 days after treatment.
- VAGLOR powder for oral solution and reconstituted solution should be handled with caution. If the powder or solution makes direct contact with skin, the area should be washed thoroughly with soap and water. If the solution gets into the eye, the eye should immediately be thoroughly washed with water.

Children and adolescents

Safety and efficacy of VAGLOR use in children has not been established.

Other medicines and VAGLOR

Always tell your health care provider if you are taking any other medicine. (this included all complementary or traditional medicines). The use of VAGLOR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you are already taking medicines that contain any of the following:

- Imipenem-cilastatin (an antibiotic). Taking this with VAGLOR can cause convulsions (fits).
- Zidovudine, didanosine, lamivudine, tenofovir, abacavir, emtricitabine or similar kinds of medicines used to treat AIDS. Your doctor may reduce the dose of didanosine that you need to take.

- Probenecid (a medicine against gout). Taking probenecid and VAGLOR at the same time could increase the amount of ganciclovir in your blood.
- Mycophenolate mofetil (used after organ transplantations).
- Vincristine, vinblastine, adriamycin, hydoxyurea or similar kinds of medicines to treat cancer.
- Trimethoprim, trimethoprim/sulpha combinations and dapsone (antibiotics).
- Pentamidine (medicine to treat parasite or lung infections).
- Flucytosine or amphotericin B (antifungal medicines).

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 health care provider for advice before taking VAGLOR.

Pregnancy

VAGLOR should not be given to pregnant women because it is possible that this could lead to the loss of the baby or to the birth of a malformed baby or to problems in the baby after birth.

Breastfeeding

You must not take VAGLOR if you are breastfeeding. If your doctor wants you to begin treatment with VAGLOR you must stop breastfeeding before you start to take your oral solution.

Fertility

It is also extremely important that both men and women of childbearing age use effective contraception when taking VAGLOR. if you need advice on contraception, ask your doctor before you start to take VAGLOR. Men whose partners could become pregnant should use condoms while taking VAGLOR and should continue to use condoms for 90 days after treatment has finished. Women should use effective contraception during treatment and for 30 days after treatment.

Driving and using machines

VAGLOR may make you feel dizzy, tired, sleepy, shaky or confused.

VAGLOR may impair your ability to drive and use machines. Do not drive, operate machinery, or do anything else that could be dangerous until you know how VAGLOR affects you.

VAGLOR powder for oral solution contains sodium benzoate. Benzoate salt may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

3. How to take VAGLOR

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

Always take VAGLOR exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Induction treatment of CMV retinitis

For patients with active CMV retinitis, the recommended dose is 900 mg VAGLOR twice a day for 21 days. Prolonged induction treatment may increase the risk of bone marrow toxicity.

Maintenance treatment of CMV retinitis

Following induction treatment, or in patients with inactive CMV retinitis, the recommended dose is 900 mg VAGLOR once daily.

Prevention of CMV disease in solid organ transplantation

For kidney transplant patients, the recommended dose is 900 mg once daily depending on creatinine clearance (kidney function test), starting within 10 days of transplantation until 200 days post (after)-

transplantation.

For patients who have received a solid organ transplant other than the kidney, the recommended dose is 900 mg daily, starting within 10 days of transplantation until 100 days post (after)- transplantation.

VAGLOR should be taken with food. If you are unable to eat for any reason, you should still take your dose of VAGLOR as usual.

Your doctor will prescribe appropriate dose according to your condition. It is important to follow the dosage strictly to avoid overdose.

It is important that you use the syringe provided in the pack to measure your dose of VAGLOR.

Your doctor will tell you how long your treatment with VAGLOR will last. Do not stop treatment early. If you have the impression that the effect of VAGLOR is too strong or too weak, tell your doctor or pharmacist.

If you take more VAGLOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Taking too much VAGLOR can cause serious side effects, particularly affecting your blood or kidneys.

If you forget to take VAGLOR

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take VAGLOR at the next regularly scheduled time.

Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with VAGLOR is stopped:

You must not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

VAGLOR can have side effects.

Not all side effects reported for VAGLOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VAGLOR, please consult your health care provider for advice.

If any of the following happens, stop taking VAGLOR 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,
- rash or itching,
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to VAGLOR. 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:

- fever, fatigue, sore throat, swollen lymph glands – these may be signs of infection due to a reduction in the number of your white blood cells bruising and bleeding, which may indicate a change in your blood cells
- feeling short of breath or having trouble breathing (dyspnoea)
- blurred vision, inability to see in dim light, partial loss of vision, seeing flashes of light, seeing spots, sensitivity to light, vision loss these may indicate a detached retina
- inflammation of cellular tissue (cellulitis), inflammation or infection of the kidneys or bladder

- a rise in some liver enzymes, which will only be seen during blood tests
- changes to the normal working of the kidneys
- depression
- deafness
- inflammation of the pancreas (pancreatitis) where you may notice severe pain in the stomach and back
- blood in the urine, kidney failure

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- fungal infection in the mouth (oral candidiasis), infections caused by bacteria or viruses in the blood
- swollen stomach, mouth ulcers
- diarrhoea
- a reduction in the pigment in the blood that carries oxygen (anaemia) - which can cause tiredness and breathlessness
- headache
- red, swollen eyes (conjunctivitis), abnormal vision
- difficulty sleeping
- strange tastes
- decreased sense of touch
- prickly or tingling skin
- loss of feeling in the hands or feet
- dizziness
- fits (convulsions)

- eye pain, swelling within the eye
- earache
- coughing
- feeling sick (nausea) and being sick (vomiting), stomach ache, constipation, wind, indigestion, difficulty swallowing
- inflamed skin, itching, sweating at night, hair loss (alopecia)
- back pain, pain in the muscles or joints, stiff muscles, muscle cramps
- loss of appetite (anorexia), weight loss
- tiredness, fever, pain, loss of energy, generally feeling unwell
- feeling anxious, confused, having unusual thoughts
- chest pain
- low blood pressure, which can cause you to feel light-headed or faint

Less frequent:

- changes to your normal heartbeat
- shaking or trembling
- itchy rash or swellings (urticaria), dry skin
- a rise in the liver enzyme called alanine aminotransferase (which will only be seen during blood tests)
- having unusual changes in mood and behaviour, losing contact with reality such as hearing voices or seeing things that are not there, feeling agitated
- infertility in men

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 or pharmacist. You can also report side effects to SAHPRA via the "Adverse drug reaction and quality problem reporting form", found online under SAHPRA's publications: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem- reporting-form/. or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com. By reporting side effects, you can help provide more information on the safety of VAGLOR.

5. How to store VAGLOR

- Store at or below 25 °C.
- Reconstituted solution to be stored not longer than 49 days at 2 °C to 8 °C.
- Protect from light and moisture.
- Bottle must be kept tightly-closed.
- Keep the bottle in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the 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 VAGLOR contains

- The active substance is valganciclovir hydrochloride.
- The other ingredients are anhydrous citric acid, mannitol, povidone, sodium benzoate, saccharin sodium, purified water, Tutti – Frutti flavour 051880 AP0551 contains maize maltodextrin, flavourings, INS 1520 polypropylene glycol, INS 307 c dl-alpha-tocopherol

What VAGLOR looks like and contents of the pack

VAGLOR is white to slightly yellow coloured powder. The constituted solution is a colourless to brownish yellow tutti-frutti flavoured clear solution.

Contents of the pack

VAGLOR powder for oral solution:

12 grams of powder in 120 ml molded amber colored type I glass bottle with 28 mm screw type neck finish with white opaque polypropylene, ribbed, child resistant plastic caps with opening illustrations embossed on top. The bottles come with 2 10 mL oral dosing syringes with a white opaque tip cap and clear adapter with printed graduation marks from 1 mL to 10,0 mL and each 0,5 mL on barrel.

Bottle is enclosed in an outer carton until required for use.

Holder of Certificate of Registration

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This leaflet was last revised in

05 September 2023

Registration number(s)

540273.271

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Access to the corresponding Professional Information

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