PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

VALACICLOVIR 500 UNICORN

Each film coated tablet contains 500 mg of valaciclovir.

VALACICLOVIR 1000 UNICORN

Each film coated tablet contains 1000 mg of valaciclovir.

VALACICLOVIR UNICORN is sugar free.

Read all of this leaflet carefully before you start taking VALACICLOVIR UNICORN.

- 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.
- **VALACICLOVIR UNICORN** 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 **VALACICLOVIR UNICORN** is and what it is used for
2. What you need to know before you take **VALACICLOVIR UNICORN**
3. How to take **VALACICLOVIR UNICORN**
4. Possible side effects
5. How to store **VALACICLOVIR UNICORN**
6. Contents of the pack and other information

1. What VALACICLOVIR UNICORN is and what it is used for

VALACICLOVIR UNICORN belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses and can be used to:

- Treat herpes zoster (shingles).
- Treat repeated genital herpes simplex infections (a common sexually transmitted virus infection).
- Prevent repeated herpes simplex infections of the skin and mucous membranes (the inner surface) of the anus and genital areas.
- Prevent cytomegalovirus infection or disease after an organ transplant.

2. What you need to know before you take VALACICLOVIR UNICORN Do not take VALACICLOVIR UNICORN:

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine listed in section 6.

Take special care with VALACICLOVIR UNICORN

Talk to your doctor or pharmacist before taking **VALACICLOVIR UNICORN**

- if you have advanced HIV disease, or had a bone marrow transplant or kidney transplant.

  These patients have a higher chance of getting a blood disorder, (thrombotic, thrombocytopenic purpura/haemolytic uremic syndrome) which can result in death.
- if you have kidney problems
- if you are elderly (65 years of age or older)
- if you have liver problems
- if your immune system is weak

Prevent passing genital herpes on to others:

Genital herpes is a sexually transmitted disease. If you are taking **VALACICLOVIR UNICORN** to treat or prevent genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You can spread genital herpes to others, even when you have no symptoms. You should not have sex if you have genital sores or blisters.

Other medicines and VALACICLOVIR UNICORN

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

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

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include:

aminoglycosides (an antibiotic), organoplatinum compounds (anti-cancer medicine), iodinated contrast media (used in radiology), methotrexate (used in treating rheumatoid arthritis, for example), pentamidine (antimicrobial), foscarnet (antiviral), cimetidine (used in treating reflux, for example), probenecid (used in treating gout, for example).and immunosuppressant medicines such as ciclosporin and tacrolimus.

Before you stop taking any of your medicines, please talk to your doctor first.

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 this medicine.

VALACICLOVIR UNICORN is not usually recommended for use during pregnancy. Your doctor will weigh up the benefits and risks of treatment before prescribing **VALACICLOVIR UNICORN** if

you are pregnant or breastfeeding.

Driving and using machinery

VALACICLOVIR UNICORN can cause side effects that affect your ability to drive. Do not drive or use machinery unless you are sure you are not affected.

It is not always possible to predict to what extent **VALACICLOVIR UNICORN** 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 **VALACICLOVIR UNICORN** affects them.

3. How to take VALACICLOVIR UNICORN

- Do not share medicines prescribed for you with any other person.
- Always take **VALACICLOVIR UNICORN** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- The dose of **VALACICLOVIR UNICORN** and duration of treatment will depend on why your doctor has prescribed **VALACICLOVIR UNICORN** for you. Your doctor will discuss this with you.
- the score line on **VALACICLOVIR UNICORN 1000** is only there to help you break the tablet if you have difficulty swallowing it whole

Your doctor may adjust the dose of VALACICLOVIR UNICORN:

- if you are over 65 years of age
- if you have a weak immune system
- if you have kidney problems.

Talk to your doctor before taking **VALACICLOVIR UNICORN** if any of the above applies to you.

It is important while you are taking **VALACICLOVIR UNICORN** that you drink water regularly.

This will help to reduce side effects that can affect the kidneys or the nervous system. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy. Please consult your doctor should you experience these side effects.

If you take more VALACICLOVIR UNICORN than you should

If you take too many tablets you may feel sick, vomit, get kidney problems, may be confused, agitated, feel less aware, see things that are not there, or become unconscious. If you take too much **VALACICLOVIR UNICORN**, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take VALACICLOVIR UNICORN

If you have missed a 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 **VALACICLOVIR UNICORN** at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

VALACICLOVIR UNICORN can have side effects.

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

If any of the following happens, stop taking **VALACICLOVIR UNICORN** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- flushing,
- itchy skin rash,
- swelling of the lips, face, neck and throat, causing difficulty in breathing (angioedema),

- fall in blood pressure, leading to collapse.

These are all very serious side effects. If you have them, you may have had a serious reaction to **VALACICLOVIR UNICORN**. 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 less frequent side effects:

- feeling confused
- seeing or hearing things that aren't there (hallucinations)
- feeling very drowsy
- tremors
- feeling agitated
- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts (delirium)

These are all serious side effects. You may need urgent medical attention. These side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of **VALACICLOVIR UNICORN** (8 g or more) a day. They usually get better when **VALACICLOVIR UNICORN** is stopped or the dose reduced.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache
- feeling sick (nausea)
- dizziness

- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (photosensitivity).
- rash
- itching (pruritus)

Less frequent side effects

- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)
- blood in urine (haematuria)
- kidney problems where you pass little or no urine.
- reduction in the number of white blood cells (leucopenia)
- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver.

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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.
Side effects must also be reported to Unicorn Pharmaceuticals (Pty) Ltd to vigilance@unicornpharma.co.za.

By reporting side effects, you can help provide more information on the safety of **VALACICLOVIR UNICORN.**

5. How to store VALACICLOVIR UNICORN

- Store all medicines out of reach of children.
- Store at or below 25 ºC.
- Keep the tablets dry and protect from light.
- Keep blisters in outer carton until required for use.
- Do not use the tablets after the expiry date printed on the container.
- 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 VALACICLOVIR UNICORN contains

- The active substance is: valaciclovir.
- The other ingredients are: microcrystalline cellulose, crospovidone, hypromellose and magnesium stearate.

  Film coating

  VALACICLOVIR UNICORN: Opadry blue which contains hypromellose, titanium dioxide, macrogol, indigo carmine aluminium lake and polysorbate 80.

What VALACICLOVIR UNICORN looks like and contents of the pack VALACICLOVIR 500 UNICORN: Blue colored, capsule shaped, film coated tablets debossed with '324 500' on one side and plain on the other side.

VALACICLOVIR 1000 UNICORN: Blue colored, capsule shaped, film coated tablets, with partial score bar on both sides and debossed with '325 1000' on one

side and plain on the other side. The score line is only there to help you break the tablet if you

have difficulty swallowing it whole.

VALACICLOVIR UNICORN are packed in blister packs. The blister packs are thermo formable blisters consisting of a lidding foil, which is a plain, aluminium foil coated with heat sealable lacquer, and base film (forming) comprising of a transparent PVC film.

VALACICLOVIR UNICORN:

Blister of 10 or 6 tablets. Pack size: 10, 30, 42, 60 or 100 tablets.

Holder of Certificate of Registration

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