PROPOSED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

HERPIVA 500 mg (film coated tablet)

HERPIVA 1 g (film coated tablet)

Valaciclovir 500 mg & 1 g film coated tablets.

Sugar free

Read all this leaflet carefully before you start taking HERPIVA.

- 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.
- **HERPIVA** 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 **HERPIVA** is and what it is used for

2. What you need to know before you take **HERPIVA**

3. How to take **HERPIVA**

4. Possible side effects

5 How to store **HERPIVA.**

6. Contents of the pack and other information

1. What HERPIVA is and what is it used for:

HERPIVA belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

HERPIVA *can be used to:*

• treat shingles (in adults)

• treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.

• treat cold sores (in adults and adolescents over 12 years old)

• prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)

• treat and prevent HSV infections of the eye that continue to come back (in adults and adolescents over 12 years old)

2. What you need to know before you take HERPIVA:

Do not take ***HERPIVA***

- if you are hypersensitive (allergic) to valaciclovir or aciclovir or any of the other ingredients of this **HERPIVA** (listed in Section 6).

Warnings and precautions

Take special care with ***HERPIVA,***

Before you start taking **HERPIVA**, tell your doctor if**:**

- you have had a bone marrow transplant or kidney transplant, or

  if you have advanced HIV disease or AIDS. Patients with this condition have a higher chance for getting a blood disorder, (thrombotic, thrombocytopenic purpura/hemolytic uremic syndrome) which can result in death.

- you have kidney problems,
- you are elderly (65 years of age or older),
- you have liver problems,
- you are an elderly patient,
- you have a weak immune system,
- you are dehydrated,
- you develop signs of nervous system side-effects; you will be closely monitored by your doctor. This might include feeling confused or agitated or feeling unusually sleepy or drowsy.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

Prevent passing genital herpes on to others:

HERPIVA (or any other antiviral) is not a cure for genital herpes, if you are taking HERPIVA 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. Genital herpes is a sexually transmitted disease therefore you should avoid contact with lesions (sores or blisters), damaged skin/mucosa or intercourse when lesions and/or symptoms are present to avoid infecting others. Genital herpes can also be spread if you have no symptoms, whilst the virus is making copies of itself (during asymptomatic viral shedding).

Other medicines and HERPIVA:

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

These include:

- Other medicines that affect the kidneys, e.g. aminoglycosides (gentamycin, tobramycin) organoplatinum compounds, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus.
- Cimetidine, probenecid and tenofovir taken with **HERPIVA** can cause increased levels **HERPIVA** in your body.
- Medicines that supress your immune system e.g. mycophenolate mofetil taken with **HERPIVA** can increase the levels of **HERPIVA** in your body.

Always tell your doctor or pharmacist about other medicines if you are taking **HERPIVA** for treatment of shingles or after having an organ transplant.

Pregnancy and 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 **HERPIVA**.

HERPIVA is not usually recommended for use during pregnancy.

Driving and using machines:

HERPIVA can cause side effects that affect your ability to drive.

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

3. How to take HERPIVA:

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

Always take **HERPIVA** exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Treatment of herpes zoster/shingles

• The usual dose is 1 g (one 1 g tablet or two 500 mg tablets) three times a day for seven days.

Treatment of HSV infections of the skin and genital herpes

• The usual dose is 500 mg twice a day.

• For the first infection you should take **HERPIVA** for five days or for up to ten days if your doctor tells you to. For recurrent infection, the duration of treatment is normally 3 - 5 days.

Helping to prevent HSV infections from returning after you have had them.

• The usual dose is one 500 mg tablet once a day.

• You should take **HERPIVA** until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)

• The usual dose is 2000 mg (two 1 g tablets or four 500 mg tablets) four times a day (6 hours apart).

• You will usually start taking **HERPIVA** as soon as possible after your surgery.

• You should take **HERPIVA** for around 90 days after your surgery, until your doctor tells you to stop.

*Your doctor may adjust the dose of **HERPIVA** if:*

• you are over 65 years of age

• you have a weak immune system

• you have kidney problems.

Talk to your doctor before taking **HERPIVA** if any of the above apply.

People over 65 years of age or with kidney problems

It is very important while you are taking **HERPIVA** that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated or feeling unusually sleepy or drowsy.

Taking this medicine

• Take this medicine by mouth.

• Swallow the tablets whole with a drink of water.

• Take **HERPIVA** at the same time each day.

If you take more HERPIVA than you should:

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

You may experience nausea and vomiting and an increased intensity of other side effects (listed in section 4).

If you forget to take a dose of HERPIVA:

- If you forget to take **HERPIVA**, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

HERPIVA can have side effects.

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

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

Severe allergic reactions (anaphylaxis). These are rare in people taking **HERPIVA**. Rapid development of symptoms including:

• flushing, itchy skin rash

• swelling of the lips, face, neck, and throat, causing difficulty in breathing (angioedema)

• fall in blood pressure leading to collapse. Skin rashes or redness. The adverse reaction of the skin may appear as rashes with or without blisters. Skin irritation, oedema (DRESS syndrome) and fever and flu like symptoms may occur.

These are all very serious side effects. If you have them, you may have had a serious reaction to **HERPIVA**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness,
- headache,
- vomiting,

- diarrhoea,
- nausea,
- skin reaction after exposure to sunlight,
- rash,
- itching.

Less frequent side effects:

- feeling confused,
- seeing or hearing things that are not there,
- feeling drowsy,
- tremors,
- feeling agitated,
- shortness of breath,
- stomach discomfort,
- hive-like rash,
- low back pain,
- blood in urine,
- unsteadiness when walking,
- slow slurred speech,
- fits,
- altered brain function,
- unconsciousness,
- confused or disturbed thoughts,
- inability to pass urine.

less frequent side effects that may show up in your laboratory tests:

- reduction in the number of your white blood cells,
- reduction in the number of your blood platelets
- increase in substance produced by your 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. You can also report side effects to SAHPRA via the "**6.04 Adverse drug Reaction reporting Form**", found online under SAHPRA's publications: https://sahpra.org.za/wp-content/uploads/2020/01/6.04_ARF1_v5.1_27Jan2020.pdf. By reporting side effects, you can help provide more information on the safety of **HERPIVA.**

5. How to store HERPIVA

- Store all medicine out of reach of children.
- Store at below or below 25 °C in original container.
- Protect from moisture.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

6. Contents of the pack and other information

What HERPIVA contains:

Active substance: valaciclovir hydrochloride

The other ingredients are: crospovidone, FD&C blue #2/indigo carmine aluminum lake, hypromellose, macrogol, magnesium stearate, microcrystalline cellulose, polysorbate, purified water, titanium dioxide

What HERPIVA looks like and contents of the pack

Film-coated tablets

HERPIVA 500 mg: Blue coloured, capsule shaped, film coated tablets debossed with “C 324 500” on one side and plain on the other side.

HERPIVA 1 g: Blue coloured, capsule shaped, film coated tablets with partial score bar on both sides debossed with “C 325 1000” on one side and plain on the other side.

HERPIVA 500 mg:

(60’s): blister of 10 tablets and 6 blisters in a carton.

HERPIVA 1 g:

(10’s): blister of 10 tablets and 1 blister in a carton.

Holder of Certificate of Registration

Innovata Pharmaceuticals

Crownwood Office Park

100 Northern Parkway

Ormonde

Johannesburg

2091

South Africa

Contact Information: regulatory@innovata.co.za or +27 86 999 0912

This leaflet was revised in

New PI date of registration: 03/10/2023

Date of revision of text: 18/02/2025

Registration number

HERPIVA 500 mg: A 55/20.2.8/0734

HERPIVA 1 g: A 55/20.2.8/0735

Access to the corresponding Professional information.

Follow the link for the corresponding Professional Information for HERPIVA:

pi-pil-repository.innovata.co.za,

alternatively please scan the QR code below: