1.3.2 Proposed Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ACICLOVIR 250 VIATRIS (powder for solution for injection)

ACICLOVIR 500 VIATRIS (powder for solution for injection)

Aciclovir

ACICLOVIR 250 VIATRIS contains sodium: 49 mg per 10 ml vial.

ACICLOVIR 500 VIATRIS contains sodium: 98 mg per 20 ml vial.

Sugar free

Read all of this leaflet carefully before you are given ACICLOVIR VIATRIS

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse, or other healthcare professional.

ACICLOVIR VIATRIS has been prescribed to 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 ACICLOVIR VIATRIS is and what it is used for.

2. What you need to know before you are given ACICLOVIR VIATRIS.

3. How to use ACICLOVIR VIATRIS.

1.3.2 Proposed Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

4. Possible side effects.

5. How to store ACICLOVIR VIATRIS.

6. Contents of the pack and other information.

1. What ACICLOVIR VIATRIS is and what it is used for

What ACICLOVIR VIATRIS is:

ACICLOVIR VIATRIS belongs to a group of medicines called antivirals and works by preventing the multiplication of the virus in the body that causes an infection.

What ACICLOVIR VIATRIS is used for:

ACICLOVIR VIATRIS is used to treat various viral infections, e.g. shingles and chickenpox.

2. What you need to know before you are given ACICLOVIR VIATRIS

ACICLOVIR VIATRIS should not be administered to you:

If you are hypersensitive (allergic) to aciclovir or any of the other ingredients of ACICLOVIR VIATRIS (listed in section 6).

Warnings and precautions

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

- Are pregnant or want to become pregnant.
- Are breastfeeding your baby.
- Have or had kidney or liver problems.
- Are dehydrated (water/fluid loss in the body).

- Have conditions affecting your brain or nervous system.

Take special care with ACICLOVIR VIATRIS:

- ACICLOVIR VIATRIS should be used with caution in patients with renal (kidney) impairment.
- If you are elderly.
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) has been reported with the use of aciclovir. 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.

Other medicines and ACICLOVIR VIATRIS

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ACICLOVIR VIATRIS with these medicines may cause undesirable interactions. Always tell your healthcare professional if you are taking any other medicines (this includes complementary or traditional medicines).

Please consult your doctor, pharmacist, or other healthcare professional, for advice.

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

- Do not use ACICLOVIR VIATRIS together with probenecid (treatment for gout), as it decreases renal (kidney) excretion.
- Medicines used to treat ulcers such as cimetidine.

- Mycophenolate mofetil, ciclosporin, and tacrolimus, medicines used to lower your body's natural immunity in patients who receive organ transplants.

Pregnancy and breastfeeding and fertility

If you are pregnant or breast feeding your baby, think you may be pregnant or are planning to have a baby while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice before you are given ACICLOVIR VIATRIS.
The safe use of ACICLOVIR VIATRIS has not been established in pregnant and breast-feeding patients.

Driving and using machinery

It is not always possible to predict to what extent ACICLOVIR VIATRIS may interfere with the daily activities of a patient. As ACICLOVIR VIATRIS may cause dizziness, confusion and hallucinations, patients should ensure that they do not engage in the above activities until they are aware of the measure to which ACICLOVIR VIATRIS affects them.

ACICLOVIR VIATRIS contains sodium

ACICLOVIR 250 VIATRIS contains 49 mg sodium per 10 ml, equivalent to 2,45 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.
ACICLOVIR 500 VIATRIS contains 98 mg sodium per 20 ml, equivalent to 4,9 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.
ACICLOVIR VIATRIS is sugar free.

3. How to receive ACICLOVIR VIATRIS

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

You will not be expected to give yourself ACICLOVIR VIATRIS. It will be given to you by a person who is qualified to do so. Your healthcare professional will decide on the correct dose for you.

This medicine will be administered by slow intravenous infusion (into a vein) over 1 hour.
The treatment will usually be for 5 days.

Your doctor will tell you how long your treatment with ACICLOVIR VIATRIS will last.

If you have the impression that the effect of ACICLOVIR VIATRIS is too strong or too weak, tell your doctor or pharmacist.

If you are given more ACICLOVIR VIATRIS than you should

Since a healthcare professional will administer ACICLOVIR VIATRIS, he/she will control the dose. However, in the event of overdose your doctor will manage the overdose.
If you have been given too much ACICLOVIR VIATRIS, you may:

- Feel confused and agitated.
- See or hear things that are not there (hallucinations).
- Have fits (seizures).
- Become unconscious (coma).

If you missed a dose of ACICLOVIR VIATRIS

Since a healthcare professional will administer ACICLOVIR VIATRIS, it is unlikely that the dose will be missed.

4. Possible side effects

ACICLOVIR VIATRIS can have side effects.
Not all side effects reported for ACICLOVIR VIATRIS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ACICLOVIR VIATRIS, please consult your doctor, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop taking ACICLOVIR VIATRIS 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 ACICLOVIR VIATRIS. You may need urgent medical attention or hospitalisation.

1.3.2 Proposed Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Inflammation of the veins causing pain, discomfort and swelling in the body.

The following side effects have been reported less frequently:

- Blood disease such as aneamia (reduced number of red blood cells), leukopenia (decrease in white blood cells) or low number of platelets.
- Lowering in your blood pressure.
- Headaches, tiredness, fever, dizziness, irritation, confusion, and coma.
- Seeing experiences that appear real but are not (hallucination).
- Shortness of breath.
- Nausea, vomiting, diarrhoea, stomach pains.
- Liver disease (yellowing of the eyes and/or skin).
- Hair loss.
- Kidney problems or disease.
- Discoloured or blood in your urine.
- Rashes, itching, swelling of the skin (angioedema), photosensitivity (extreme sensitivity to the sun).

The following side effects have been reported but the frequency is unknown:

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rashes, high

body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement *(see section 2).*

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

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 ACICLOVIR VIATRIS.

5. How to store ACICLOVIR VIATRIS

- *Before reconstitution:* Store at or below 25 ^{o}C. Keep containers dry and tightly closed.
- *After reconstitution:* After reconstitution with water for injections, the solution can be stored for 12 hours when stored at or below 25 ^{o}C. Preferably use the reconstituted solution immediately.
- After reconstitution/dilution in a suitable intravenous fluid, the solution can be stored for 12 hours when stored at or below 25 ^{o}C.

- Do not store reconstituted solution in refrigerator.
- ACICLOVIR VIATRIS is a single dose vial, discard any unused portion.
- KEEP OUT OF THE REACH OF CHILDREN.
- Store in the original package / container.
- Protect from light / moisture.
- 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 ACICLOVIR VIATRIS contains:

The active ingredient is aciclovir sodium.

ACICLOVIR 250 VIATRIS: Each 10 ml vial contains aciclovir sodium corresponding to aciclovir 250 mg.

ACICLOVIR 500 VIATRIS: Each 20 ml vial contains aciclovir sodium corresponding to aciclovir 500 mg.

The other ingredients are sodium hydroxide, sodium hydroxide solution and water for injection.

What ACICLOVIR VIATRIS looks like and contents of the pack:

1.3.2 Proposed Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

What ACICLOVIR VIATRIS looks like

ACICLOVIR 250 VIATRIS: *Before reconstitution:* White or almost white freeze-dried powder.

After reconstitution: Clear, colourless solution.

ACICLOVIR 500 VIATRIS: *Before reconstitution:* White or almost white freeze-dried powder.

After reconstitution: Clear, colourless solution.

Contents of the pack

ACICLOVIR 250 VIATRIS: Packs of 5 x 10 ml clear, colourless, Type I glass vials with lyophilisation stoppers made from grey bromobutyl rubber and flip-off aluminium capsules.

ACICLOVIR 500 VIATRIS: Packs of 5 x 20 ml clear, colourless, Type I glass vials with lyophilisation stoppers made from grey bromobutyl rubber and flip-off aluminium capsules.

Holder of Certificate of Registration and Manufacturer

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1.3.2 Proposed Patient Information Leaflet

1.5.5.2 Patient Information Leaflet **-CLEAN**

Registration numbers

ACICLOVIR 250 VIATRIS: 42/20.2.8/0069

ACICLOVIR 500 VIATRIS: 42/20.2.8/0070

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website.