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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

LOVIRE® 200 and LOVIRE® 400 Tablets

Aciclovir

Sugar free

Read all of this leaflet carefully before you start taking LOVIRE® TABLETS

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

1. What **LOVIRE®** is and what it is used for

LOVIRE® Tablets contains a medicine called aciclovir.

The active substance of **LOVIRE® Tablets** belongs to the group of medicines called antivirals.

LOVIRE® Tablets are used for:

- Treatment of cold sores and genital herpes
- Prevention of cold sores and genital herpes returning after you have had them (especially in people whose immune systems work less well, which means their bodies are less able to fight infections).
- Treatment of shingles if the lesions are not older than 72 hours.
- Treatment of chickenpox within 24 hours after appearance of the typical chickenpox lesions.
- Reduces the risk of death and cold sores as well as genital herpes for those with advanced HIV disease, when taken together with oral zidovudine (medicine used to treat HIV infections) or after bone marrow transplant.
- Treatment of patients following bone marrow transplant when taken after one month's intravenous treatment with aciclovir.*

* The applicant does not have an intravenous dosage form registered nor marketed, another acyclovir brand can be used.

2. What you need to know before you take LOVIRE®

Do not take LOVIRE® Tablets:

- if you are allergic (hypersensitive) to aciclovir, valaciclovir or any other ingredient of **LOVIRE® Tablets** (listed in section 6)

Warnings and precautions

Take special care with LOVIRE® Tablets:

Important information:

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of **LOVIRE® Tablets**. 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.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking **LOVIRE® Tablets** and contact your doctor or seek medical attention immediately.

Tell your doctor:

- if you have kidney problems as the dosage you should take may need to be adjusted
- if you are dehydrated (a condition in which your body does not have as much water and fluids as it should)
- if you are elderly (over 65 years of age)
- if you experience nausea and vomiting
- if you experience headache and confusion

If you take too much **LOVIRE® Tablets** over several days you may experience gastrointestinal effects (such as nausea and vomiting) and neurological effects (such as headache and confusion).

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking **LOVIRE® Tablets**

Elderly

If you are over 65 years of age, ensure that you take plenty of water at all times while taking high doses of **LOVIRE® Tablets**, as **LOVIRE® Tablets** may take longer leave your body than in younger patients.

The doctor will ensure to reduce your dosage if you have kidney problems.

Other medicines and LOVIRE® Tablets

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines).

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- probenecid (medicine used to treat gout)
- cimetidine (used to treat heartburn and peptic ulcers)
- medicines that can cause kidney damage (nephrotoxic medicines) e.g.

antibiotics (aminoglycosides, amphotericin B)

- painkillers (acetaminophen)
- medicine used to treat psychiatric problem (lithium)
- medicine used to treat cancer (methotrexate)

Pregnancy, breastfeeding and fertility

The safety in pregnancy and lactation has not been established.

If you are taking **LOVIRE® Tablets**, you should not breastfeed your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LOVIRE® Tablets**.

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.

Safety and efficacy in pregnancy and lactation has not been established. The use of **LOVIRE® Tablets** during pregnancy and breastfeeding is therefore not recommended.

Driving and using machines

LOVIRE® Tablets may cause dizziness.

It is not always possible to predict to what extent **LOVIRE® Tablets** 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 **LOVIRE®** affects them.

3. How to take LOVIRE® Tablets

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

Always take **LOVIRE® Tablets** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Take **LOVIRE® Tablets** by mouth.

- Dissolve the tablet in a glass of water (50 mL) and stir before drinking.
- If you prefer, the tablet can also be swallowed whole with a little water.
- **LOVIRE® Tablets** may be taken with meals or without meals

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

If you take more LOVIRE® Tablets than you should

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

The symptoms reported for overdosage are: nausea and vomiting, headache and confusion

If you forget to take LOVIRE® Tablets

If you forget to take **LOVIRE® Tablets**, 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.

If you stop taking LOVIRE® Tablets

Do not stop taking **LOVIRE® Tablets** just because you feel better. It is important that you complete your course of tablets to effectively treat an outbreak of herpes, or to reduce further outbreaks if you are taking **LOVIRE® Tablets** long term. Your doctor will advise you when to stop taking **LOVIRE® Tablets**.

4. Possible side effects

LOVIRE® Tablets can have side effects.

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

If any of the following happen, stop taking LOVIRE® Tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body
- shortness of breath, wheezing or trouble in breathing
- extensive skin rash that is accompanied by fever, swollen lymph nodes and swelling in the face (Drug reaction with eosinophilia and systemic symptoms (DRESS))

These are **very serious** side effects. 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:

- Blood in urine or stool
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- Fluid retention causing swelling in legs, ankles or feet
- Hallucinations, convulsions or tremors

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Dizziness
- Nausea
- Vomiting
- Diarrhoea
- Abdominal pain
- Fatigue

- Fever

Less frequent side effects:

- Weakness
- Cold feet and hands
- Chills
- Sweating
- Sore throat
- Easily bruised
- Bleeding from gums or nose
- Abdominal pain
- Pain near rectum
- Pain when urinating
- Loss of appetite
- Shortness of breath
- Hair loss

Frequency unknown:

- Drowsiness
- Confusion
- Restlessness
- Coma

If you notice any side effect 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 “6.04 Adverse Drug Reaction 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 **LOVIRE® Tablets**.

5. How to store LOVIRE® Tablets

- Store at or below 25 °C, protected from moisture.
- Do not use after the expiry date stated on the label.
- Return all unused medicines to your pharmacist.
- Do not dispose of unused medicines in drains or sewerage systems.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

6. Contents of the pack and other information

What LOVIRE® Tablets contains

The active substance is aciclovir.

Each dispersible tablets contains 200mg or 400 mg acyclovir

The other ingredients are: microcrystalline cellulose, sodium starch glycollate, pregelatinized maize starch, magnesium stearate, colloidal anhydrous silica.

What LOVIRE® Tablets looks like and contents of the pack

LOVIRE® 200 Tablets

Capsule shaped, biconvex, uncoated white to off-white tablets with '200' embossed on one side and 'ACV' on the other side.

LOVIRE® 400 Tablets

Capsule shaped, biconvex, uncoated white to off-white tablets with '400' embossed on one side and 'ACV' on the other side.

LOVIRE® 200 Tablets: Carton containing 25 tablets in blister strips.

LOVIRE® 400 Tablets: Carton containing 56 or 70 tablets in blister strips.

Holder of Certificate of Registration

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