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

Ranbaxy Pharmaceuticals (Pty) Ltd

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South Africa

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Botswana: S2 Reg.No.:

Lovire 200 Tablets - BOT0400704

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Lovire 200 Tablets - 04/20.2.8/1285

Lovire 400 Tablets - 04/20.2.8/1286

1 **PASIËNTINLIGTINGSTUK**

SKEDULERINGSTATUS

S4

LOVIRE® 200 en LOVIRE® 400 Tablette

Asiklovir

Suikervry

Lees hierdie hele inligtingstuk noukeurig deur voordat jy begin om LOVIRE® TABLETS te neem

Hou hierdie inligtingstuk. Dit mag moontlik vir jou nodig wees om dit weer te lees.

- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **LOVIRE® TABLETS** is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs as hulle simptome dieselfde as joune is.

Wat is in hierdie inligtingstuk

1. Wat **LOVIRE®** is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy **LOVIRE®** neem
3. Hoe om **LOVIRE®** te neem
4. Moontlike newe-effekte
5. Hoe om **LOVIRE®** te bewaar
6. Inhoud van die verpakking en ander inligting

1. Wat LOVIRE® is en waarvoor dit gebruik word

LOVIRE® Tablets bevat ‘n middel wat asiklovir genoem word.

Die aktiewe bestanddeel van **LOVIRE® Tablets** behoort aan ‘n groep van medisyne wat antivirale middels genoem word.

LOVIRE® Tablets word gebruik vir:

- Behandeling van koorblare en genitale herpes
- Voorkoming van koorsblare en genitale herpes wat terugkeer nadat jy dit gehad het (veral in persone wat se immuunstelsels nie behoorlik funksioneer nie, wat beteken dat hulle liggame minder in staat is om infeksies te beveg).
- Behandeling van gordelroos indien die letsels nie ouer as 72 uur is nie.
- Behandeling van waterpokkies binne 24-uur ná voorkoms van die tipiese waterpokkie-letsels.
- Verminder die risiko van sterfte en koorsblare asook genitale herpes vir dié met gevorderde MIV-siekte, wanneer saam met orale sidovudien (medisyne wat gebruik word om MIV-infeksies te behandel) geneem word of ná beenmurgoorplanting.
- Behandeling van pasiënte ná beenmurgoorplanting wanneer dit geneem word ná een maand se intraveneuse behandeling met asiklovir*

  * Ranbaxy Pharmaceuticals (Pty) Ltd het nie ‘n intraveneuse geregistreerde doseervorm óf een vir bemarking nie; ‘n ander handelsmerk van asiklovir kan gebruik word.

2. Wat jy moet weet voordat jy LOVIRE® neem

Moenie LOVIRE® Tablets neem nie:

- as jy allergies (hipersensitief) is vir asiklovir, valasiklovir of enige ander bestanddeel van **LOVIRE® Tablets** (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls

Tref spesiale voorsorg met LOVIRE® Tablets:

Belangrike inligting:

Geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS) is aangemeld met die gebruik van **LOVIRE® Tablets** . DRESS vertoon aanvanklik griepagtige simptome en 'n uitslag op die gesig, dan 'n uitgebreide uitslag met 'n hoë liggaamstemperatuur, verhoogde vlakke van lewerensieme gesien in bloedtoetse en 'n toename in 'n tipe witbloedsel (eosinofilie) en vergrote limfknope. As jy 'n uitslag ontwikkel wat met koors en vergrote limfknope gepaard gaan, hou op om **LOVIRE® Tablets** te neem en kontak jou dokter of soek onmiddellik mediese hulp.

Lig jou dokter in:

- as jy nierprobleme het, aangesien dit nodig mag wees dat die dosis wat jy moet neem, aangepas moet word
- as jy ontwater is (‘n toestand waarin jou liggaam nie soveel water en vloeistowwe het as wat dit behoort te hê nie)
- as jy bejaard is (bo die ouderdom van 65 jaar)
- as jy naarheid en braking ervaar
- as jy hoofpyn en verwarring ervaar

As jy te veel **LOVIRE® Tablets** oor verskeie dae geneem het, kan jy gastroïntestinale effekte (soos naarheid en braking) en neurologiese effekte (soos hoofpyn en verwarring) ervaar.

As jy nie seker is of die bogenoemde op jou van toepassing is nie, praat met jou dokter of apteker voordat jy **LOVIRE® Tablets** neem.

Bejaardes

As jy bo die ouderdom van 65 jaar is, moet jy seker maak dat jy ten alle tye voldoende water inneem as jy hoë dosisse van **LOVIRE® Tablets** neem, aangesien **LOVIRE® Tablets** langer kan neem om jou liggaam te verlaat as by jonger pasiënte.

Die dokter sal seker maak om jou dosis te verlaag indien jy nierprobleme het.

Ander medisyne en LOVIRE® Tablets

Lig jou gesondheidsorgverskaffer altyd in as jy ander medisyne gebruik (dit sluit komplementêre of tradisionele medisyne in).

Lig jou dokter of apteker veral in as jy enige van die volgende medisyne gebruik:

- probenesied (medisyne wat gebruik word om jig te behandel)
- simetidien (gebruik om sooibrand en maagsere te behandel)
- medisyne wat nierskade kan veroorsaak (nefrotoksiese medisyne) bv.
  - antibiotika (aminoglikosiede, amfoterisien-B)
  - pynstillers (asetaminofen)
- medisyne wat gebruik word om psigiatriese probleme te behandel (litium)
- medisyne wat gebruik word om kanker te behandel (metotreksaat)

Swangerskap, borsvoeding en fertiliteit

Die veiligheid in swangerskap en laktasie is nie vasgestel nie.

As jy **LOVIRE® Tablets** neem, moet jy nie jou baba borsvoed nie.

As jy swanger is of jou baba borsvoed, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy **LOVIRE® Tablets** neem.

Indien jy swanger is of borsvoed, vermoed dat jy swanger mag wees of beplan om ‘n baba te hê, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg vir advies voordat jy hierdie medisyne gebruik.

Veiligheid en doeltreffendheid in swangerskap en laktasie is nie vasgestel nie. Die gebruik van **LOVIRE® Tablets** tydens swangerskap en borsvoeding word daarom nie aanbeveel nie.

Bestuur van voertuie en gebruik van masjinerie

LOVIRE® Tablets kan duiseligheid veroorsaak.

Dit is nie altyd moontlik om te voorspel tot watter mate **LOVIRE® Tablets** met die daaglikse aktiwiteite van ‘n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie in enige van die bogenoemde aktiwiteite betrokke raak nie totdat hulle weet tot watter mate **LOVIRE®** hulle gaan affekteer.

3. Hoe om LOVIRE® Tablets te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem **LOVIRE® Tablets** altyd presies soos wat jou dokter of apteker jou gesê het. Kontroleer met jou dokter of apteker as jy nie seker is nie.

- Neem **LOVIRE® Tablets** mondeliks.
- Los die tablet op in ‘n glas water (50 mL) en roer voordat dit gedrink word.
- As jy dit verkies, kan die tablet ook heel ingesluk word met ‘n bietjie water.
- **LOVIRE® Tablets** kan met of sonder maaltye geneem word.

Jou dokter sal jou sê vir hoe lank jou behandeling met **LOVIRE® Tablets** sal duur. Moenie vroeg met die behandeling ophou nie. As jy onder die indruk is dat die effek van **LOVIRE® Tablets** te sterk of te swak is, moet jy jou dokter of apteker inlig.

As jy meer LOVIRE® Tablets geneem het as wat jy behoort te neem

In die geval van oordosering, moet jy jou dokter of apteker raadpleeg. Indien nie een van hulle beskikbaar is nie, moet jy die naaste hospitaal of gifbeheersentrum kontak.

Die simptome wat vir oordosering aangemeld word, is: naarheid en braking, hoofpyn en verwarring.

As jy vergeet het om LOVIRE® Tablets te neem

As jy vergeet het om **LOVIRE® Tablets** te neem, neem dit so gou as wat jy onthou. As dit egter amper tyd is vir jou volgende dosis, slaan die dosis oor wat jy vergeet het.

Moenie ‘n dubbele dosis neem om vir individuele dosisse wat jy vergeet het, te vergoed nie.

As jy ophou om LOVIRE® Tablets te neem

Moenie ophou om **LOVIRE® Tablets** te neem omdat jy beter voel nie. Dit is belangrik dat jy jou kursus van tablette voltooi om die uitbraak van herpes te behandel, of om verdere uitbrake te verhoed as jy **LOVIRE® Tablets** langtermyn gebruik. Jou dokter sal jou raad gee wanneer om op te hou om **LOVIRE® Tablets** te neem.

4. Moontlike newe-effekte

LOVIRE® Tablets kan newe-effekte hê.

Nie alle newe-effekte wat vir **LOVIRE® Tablets** aangemeld word, is in hierdie inligtingstuk ingesluit nie.

Indien jou algemene gesondheid versleg of as jy ongewenste effekte ervaar terwyl jy **LOVIRE® Tablets** neem, moet jy asseblief jou gesondheidsorgverskaffer raadpleeg vir advies.

Indien enige van die volgende gebeur, staak die gebruik van LOVIRE® Tablets en lig jou dokter onmiddellik in of gaan na die noodgevalle-afdeling by jou naaste hospitaal:

- uitslag, jeuk of galbulte op jou vel
- swelling van jou gesig, lippe, tong of ander dele van jou liggaam
- kortasemigheid, hyging of probleme met asemhaling
- uitgebreide veluitslag wat gepaard gaan met koors, geswelde limfknope en swelling in die gesig (Geneesmiddel reaksie met eosinofilie en sistemiese simptome (DRESS))

Hierdie is **baie ernstige** newe-effekte. Jy mag dringende mediese aandag of hospitalisasie benodig.

Lig jou dokter onmiddellik is of gaan na die noodgevalle-afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:

- Bloed in urine of stoelgang
- Vergeling van die vel en oë, donker urine, en moegheid wat simptome van lewerprobleme kan wees
- Vogterughouding wat swelling in die bene, enkels of voete veroorsaak
- Hallusinasies, konvulsies of tremore

Lig jou dokter in indien jy enige van die volgende opmerk:

Algemene newe-effekte:

- Hoofpyn
- Duiseligheid
- Naarheid
- Braking
- Diarree
- Abdominale pyn
- Moegheid
- Koors

Minder algemene newe-effekte:

- Swakheid
- Koue voete en hande
- Kouekoors
- Sweet
- Seerkeel
- Maklike kneusing
- Bloeding van tandvleise of neus
- Abdominale pyn
- Pyn naby die rektum
- Pyn wanneer urineer
- Verlies aan aptyt
- Kortasemigheid
- Haarverlies

Voorkoms onbekend:

- Lomerigheid
- Verwarring
- Rusteloosheid

- Koma

As jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet jy asseblief jou dokter of apteker inlig.

Aanmelding van newe-effekte

Praat met jou dokter of apteker as jy newe-effekte ervaar. Jy kan ook newe-effekte SAHPRA aanmeld *via* die “6.04 Adverse Drug Reaction Reporting Form”, wat aanlyn beskikbaar is onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **LOVIRE® Tablets** te verskaf.

5. Hoe om LOVIRE® Tablets te bewaar

- Bewaar by of onder 25 °C, beskerm teen vog.
- Moenie na die vervaldatum, soos op die etiket aangedui, gebruik nie.
- Bring alle ongebruikte medisyne terug na jou apteker toe.
- Moenie van ongebruikte medisyne in dreinerings- of rioleringstelsels ontslae raak nie.

HOU BUITE DIE BEREIK EN SIG VAN KINDERS.

6. Inhoud van die verpakking en ander inligting

Wat LOVIRE® Tablets bevat

Die aktiewe bestanddeel is asiklovir.

Elke oplosbare tablet bevat 200 mg of 400 mg asiklovir.

Die ander bestanddele is: mikrokristallyne sellulose, natrium-styselglikolaat, voorafgelatiniseerde stysel, mieliestysel, magnesiumstearaat, anhidriese kolloïdale silika.

Hoe LOVIRE® Tablets lyk en inhoud van die verpakking

LOVIRE® 200 Tablets

Kapsule-vormige, bikonvekse, onbedekte wit tot naaswit tablette met `200' ingepers op een kant en `ACV' op die ander kant.

LOVIRE® 400 Tablets

Kapsule-vormige, bikonvekse, onbedekte wit tot naaswit tablette met `400' ingepers op een kant en `ACV' op die ander kant.

LOVIRE® 200 Tablets: Karton bevat 25 tablette in stulpstroke.

LOVIRE® 400 Tablets: Karton bevat 56 of 70 tablette in stulpstroke.

Houer van die Registrasiesertifikaat

Ranbaxy Pharmaceuticals (Pty) Ltd

Lautreweg 14

Stormill, Uitbreiding 1

Roodepoort, 1724

Suid-Afrika

Hierdie inligtingstuk is laas hersien op

15 August 2023

Registrasienommers

LOVIRE® 200 Tablets: 32/20.2.8/0017

LOVIRE® 400 Tablets: 32/20.2.8/0018

Botswana: S2 Reg.Nr. :

Lovire 200 Tablets - BOT0400704

Lovire 400 Tablets - BOT0400705

Namibië: NS2 Reg.Nr.:

Lovire 200 Tablets - 04/20.2.8/1285

Lovire 400 Tablets - 04/20.2.8/1286

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