APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ZELIVIRE 500 Tablets

Valaciclovir 500 mg

Sugar free

Read all of this leaflet carefully before you start taking ZELIVIRE 500

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- ZELIVIRE 500 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

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1. What ZELIVIRE 500 is and what it is used for

ZELIVIRE 500 is an antiviral medicine and it lowers the ability of the herpes viruses to multiply in your body.

ZELIVIRE 500 is used:

- to treat shingles (also called herpes zoster) in adults. Shingles is caused by the same herpes virus that causes chickenpox. It also reduces the duration of pain that is caused by the zoster virus.
- for episodic treatment of recurrent genital herpes in adult patients with normal immune systems. If you are sexually active, you can still pass herpes to your partner, even if you are taking ZELIVIRE 500.
- for prevention (suppression) of recurrent herpes simplex infection of the skin and mucous membrane of the ano-genital area.
- for prophylaxis/prevention of cytomegalovirus (CMV) infection, cytomegalovirus (CMV) disease and other herpes virus infections following organ transplantation.

2. What you need to know before you take ZELIVIRE 500

Do not take ZELIVIRE 500:

- If you are hypersensitive (allergic) to valaciclovir, aciclovir or any of the ingredients of ZELIVIRE 500 (listed in section 6).
- If you are pregnant or planning to become pregnant.
- If you are breastfeeding your baby.

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Warnings and precautions

Take special care with ZELIVIRE 500:

Important Information:

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.

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

If you had a bone marrow transplant or kidney transplant, or you have had advanced HIV disease or "AIDS". Patients with these conditions may have a higher chance for getting a blood disorder called thrombotic thrombocytopenic purpura/haemolytic uraemic syndrome (TTP/HUS). TTP/HUS can result in death.

If you have had kidney problems.

If you have liver problems.

If you are 65 years of age or older.

If you are at risk of dehydration, especially the elderly.

Ensure you drink adequate fluids.

If you have kidney problems or if you are elderly, you should be monitored by your healthcare professional as you may have an increased risk of

developing neurological side effects which is reversible when treatment with ZELIVIRE 500 is stopped.

If you have genital herpes (a sexually transmitted disease).

Taking ZELIVIRE 500 does not cure or eliminate the risk of spreading genital herpes to others. If you are taking ZELIVIRE 500 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 should not have sex if you have genital sores or blisters.

Other medicines and ZELIVIRE 500

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

Care is needed if you are taking the following medicines along with ZELIVIRE 500:

- Cimetidine (used for heart burn).
- Probenecid (used in certain joint disorders and also used to prolong the action of certain antibiotics).
- Mycophenolate mofetil, cyclosporin, and tacrolimus (used after organ transplantation).

ZELIVIRE 500 with food or drink:

ZELIVIRE 500 can be taken with or without food. Swallow the tablet with a glass of water.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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.

The safety of taking ZELIVIRE 500 during pregnancy or breastfeeding has not yet been established.

There is no fertility data available.

Driving and using machines

ZELIVIRE 500 can cause side effects that affect your ability to drive.

Do not drive or use machines unless you are sure you are not affected.

3. How to take ZELIVIRE 500

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

Always take ZELIVIRE 500 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

For the treatment of herpes zoster:

1 000 mg of ZELIVIRE 500 to be taken 3 times per day for 7 days**.**

Recurrent genital herpes:

500 mg twice daily for 5 days. Dosing should begin as early as possible.

For the prevention (suppression) of recurrences of herpes simplex infection

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*Immunocompetent patients***:** 500 mg to be taken once daily. Some patients with very frequent recurrences (e.g. 10 or more per year) may gain additional benefit from daily dose of 500 mg being taken as divided dose (250 mg twice daily).

Immunocompromised patients: 500 mg twice daily.

Prophylaxis of cytomegalovirus infection (CMV) and disease

Adults and adolescents (from 12 years of age): 2 000 mg to be taken 4 times a day.

Your doctor will tell you how long your treatment with ZELIVIRE 500 will last. If you have the impression that the effect of ZELIVIRE 500 is too strong or too weak, talk to your doctor or pharmacist.

Your dose of ZELIVIRE 500 and duration of treatment will depend on the type of herpes infection that you have and any other medical problems that you have.

Take your tablets as directed and do not stop ZELIVIRE 500 or change your treatment without consulting your doctor.

Your dose may be different if you have had problems associated with your liver and kidneys. Your doctor will decide the dose of ZELIVIRE 500 for you.

Your doctor may adjust the dose of ZELIVIRE 500 if:

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 ZELIVIRE 500 if any of the above apply.

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If you take more ZELIVIRE 500 than you should:

Do not take more than the prescribed number of ZELIVIRE 500 each day. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. In the event that an overdose has occurred with ZELIVIRE 500, aciclovir, which is the active metabolite of valaciclovir, is removable by haemodialysis (the process of blood purification when the kidneys are not working normally).

If you forget to take ZELIVIRE 500

If you miss a dose of ZELIVIRE 500, take it as soon as you remember and then take your next dose at its regular time. However, if it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time.

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

ZELIVIRE 500 can have side effects.

Not all side effects reported for ZELIVIRE 500 are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking ZELIVIRE 500, please consult your healthcare provider for advice.

If any of the following happens, stop taking ZELIVIRE 500 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.

- Rash or itching.
- Fainting.
- 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 all very serious side effects. If you have them, you may have had a serious reaction to ZELIVIRE 500. 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:

- Yellowing of the skin and eyes, also called jaundice.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache
- Feeling sick (nausea)

Less frequent side effects:

- A decrease of platelets in the blood
- Reduced number of red blood cells
- Reduced number of white blood cells
- Reduced number of neutrophils in the blood
- Feeling tired
- Dizziness

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- Feeling irritated
- Aggressive behaviour
- A feeling of confusion
- Mental confusion
- Decreased consciousness or awareness
- Hallucinations
- Tremors (shakes)
- A decrease or lack of voluntary coordination of muscle movements
- Slurred or slow speech
- Psychosis
- Sleepiness or drowsiness
- Convulsions
- Encephalopathy (a disease in which the functioning of the brain is affected by some agent or condition)
- Coma; especially in patients with kidney dysfunction where the recommended dosage was exceeded
- Vomiting
- Problems with your stomach which may include diarrhoea and stomach pains
- Inflammation of the liver
- Increased bilirubin and liver enzymes (reversible)
- Yellowing of the skin or whites of the eyes (jaundice)
- An increase in the urea and creatinine in the blood
- Severe kidney failure.

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- Hair loss.

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, pharmacist or nurse.

You can also report side effects to SAHPRA via the Med Safety APP Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Suspected adverse reactions can also be reported directly to the Holder of certificate of registration via email:

pharmacovigilance.africasme@sunpharma.com or tel: +27(0) 12 643 2000.

By reporting side effects, you can help provide more information on the safety of ZELIVIRE 500.

5. How to store ZELIVIRE 500

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package.
- Protected from light/moisture.
- Keep the blisters in the outer carton until required for use
- Do not store in a bathroom
- Do not use after the expiry date stated on the label/carton.
- 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 ZELIVIRE 500 contains

The active substance is valaciclovir hydrochloride equivalent to valaciclovir 500 mg.

The other ingredients are aluminium lake colour blue, crospovidone, magnesium stearate, microcrystalline cellulose, povidone. The film-coat contains aluminium lake, hypromellose, macrogol, polysorbate, polyethylene glycol and titanium dioxide.

What ZELIVIRE 500 looks like and contents of the pack

Blue coloured, capsule shaped, biconvex, film coated tablets, debossed with 'V' and '5' on either side of the breakline on one side, notched on either side along with the breakline and plain on the other side.

Cartons contain 30 tablets packed in PVdC coated PVC blister strips. PVdC coated PVC blister strips comprises of clear transparent PVC film, coated uniformly with PVdC on inner side with a backing of aluminium foil coated with heat seal lacquer on inner side.

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Holder of Certificate of Registration

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South Africa

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