PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

VALVIR 450 Film-coated Tablets

Valganciclovir

sugar free

Read all of this leaflet carefully before you start taking VALVIR 450

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse, or other health care provider.
- VALVIR 450 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 VALVIR 450 is and what it is used for:
2. What you need to know before you take VALVIR 450.
3. How to take VALVIR 450.
4. Possible side effects
5. How to store VALVIR 450
6. Contents of the pack and other information.

1. WHAT VALVIR 450 IS AND WHAT IT IS USED FOR

VALVIR 450 belongs to a group of medicines, which work directly to prevent the growth of viruses. The active ingredient in the tablets, valganciclovir, is changed into ganciclovir. Ganciclovir prevents a virus called cytomegalovirus (CMV) from multiplying and invading healthy cells. In patients with a weakened immune system, CMV can cause an infection in the body's organs. This can be life threatening.

VALVIR 450 is used:

- For the treatment of CMV-infections of the retina of the eye in adult patients with acquired immunodeficiency syndrome (AIDS). CMV-infection of the retina of the eye can cause vision problems and even blindness.
- To prevent CMV disease in solid organ transplant patients.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VALVIR 450

Do not take VALVIR 450

- if you are allergic to valganciclovir, ganciclovir or any of the other ingredients of this medicine (listed in **section 6**).

Warnings and precautions

Talk to your doctor or pharmacist before taking VALVIR 450:

- if you are allergic to acyclovir, penciclovir, valaciclovir or famciclovir. These are other medicines used for viral infections.

Take special care with VALVIR 450:

- if you have low numbers of white blood cells, red blood cells or platelets (small cells involved in blood clotting) in your blood. Your doctor will carry out blood tests before you start taking VALVIR 450 tablets and more tests will be done while you are taking the tablets.
- if you are having radiotherapy or haemodialysis, tell your doctor.

- if you have a problem with your kidneys. Your doctor may need to prescribe a reduced dose for you and may need to check your blood frequently during treatment.
- if you are currently taking ganciclovir capsules and your doctor wants you to switch to VALVIR 450 tablets. It is important that you do not take more than the number of tablets prescribed by your doctor or you could risk an overdose. Tell your doctor or health care provider before taking VALVIR 450.

Other medicines and VALVIR 450

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

If you take other medicines at the same time as taking VALVIR 450 the combination could affect the amount of medicine that gets into your blood stream or could cause harmful effects. Tell your doctor if you are already taking medicines that contain any of the following:

- Imipenem-cilastatin (an antibiotic). Taking this with VALVIR 450 can cause convulsions (fits)
- Zidovudine, didanosine, lamivudine, stavudine, tenofovir, abacavir, emtricitabine or similar kinds of medicines used to treat AIDS
- Adefovir or any other medicines used to treat Hepatitis B
- Probenecid (a medicine against gout). Taking probenecid and VALVIR 450 at the same time could increase the amount of ganciclovir in your blood
- Mycophenolate mofetil, ciclosporin or tacrolimus (medicines used after transplantations)
- Vincristine, vinblastine, doxorubicin, hydroxyurea or similar kinds of medicines used to treat cancer
- Trimethoprim, trimethoprim/sulpha combinations and dapsone (antibiotics)
- Pentamidine (medicines used to treat parasite or lung infections)
- Flucytosine or amphotericin B (anti-fungal medicines)

Taking VALVIR 450 with food, and drink

VALVIR 450 should be taken with food. If you are unable to eat for any reason, you should still take your dose of VALVIR 450 as usual.

Pregnancy, breastfeeding, and fertility

- You should not take VALVIR 450 if you are pregnant unless your doctor recommends it.
- If you are pregnant or planning to become pregnant you must tell your doctor. Taking VALVIR 450 when you are pregnant could harm your unborn baby.
- You must not take VALVIR 450 if you are breast-feeding.
- If your doctor wants you to begin treatment with VALVIR 450 you must stop breast-feeding before you start to take your tablets.
- Women of childbearing age must use effective contraception when taking VALVIR 450 and for at least 30 days after treatment has finished.
- Men whose partners could become pregnant should use condoms while taking VALVIR 450 and should continue to use condoms for 90 days after treatment has finished

Driving and using machines

Do not drive or use any tools or machines if you feel dizzy, tired, shaky or confused while taking this medicine.

3. HOW TO TAKE VALVIR 450

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

Always take VALVIR 450 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You have to be careful when handling your tablets. Do not break or crush them. You should swallow them whole and with food whenever possible. If you accidentally touch damaged tablets, wash your hands thoroughly with soap and water. If any powder from the tablets gets in your eyes, rinse your eyes with sterile water or clean water if you do not have sterile water.

You must stick to the number of tablets as instructed by your doctor to avoid overdose.

VALVIR 450 tablets should, whenever possible, be taken with food – see **section 2**.

Adults

Prevention of CMV disease in transplant patients

You should start to take this medicine within 10 days of your transplant. The usual dose is two tablets taken ONCE daily. You should continue with this dose for up to 100 days following your transplant. If you have received a kidney transplant, your doctor may advise you to take the dose for 200 days

Treatment of active CMV retinitis in AIDS patients (called induction treatment)

The usual dose of VALVIR 450 is two tablets taken TWICE a day for 21 days (three weeks). Do not take this dose for more than 21 days unless your doctor tells you to, as this may increase your risk of possible side effects.

Longer term treatment to prevent recurrence of active inflammation in AIDS patients with CMV retinitis (called maintenance treatment)

The usual dose is two tablets taken ONCE daily. You should try to take the tablets at the same time each day. Your doctor will advise you how long you should continue to take VALVIR 450. If your retinitis worsens while you are on this dose, your doctor may tell you to repeat the induction treatment (as above) or may decide to give you a different medicine to treat the CMV infection.

Elderly patients

VALVIR 450 has not been studied in elderly patients.

Patients with kidney problems

If your kidneys are not working properly, your doctor may instruct you to take fewer tablets each day or only to take your tablets on certain days each week. It is very important that you only take the number of tablets prescribed by your doctor.

Patients with liver problems

VALVIR 450 has not been studied in patients with liver problems.

Use in children and adolescents

Safety and efficacy have not been established in children and adolescents.

If you take more VALVIR 450 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Taking too many tablets can cause serious side effects, particularly affecting your blood or kidneys. You may need hospital treatment.

If you forget to take VALVIR 450

If you forget to take your tablets, take the missed dose as soon as you remember and take the next dose at the usual time. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

VALVIR 450 can have side effects.

Not all side effects reported for VALVIR 450 are included in this leaflet. Should your

general health worsens, or if you experience any untoward effects while taking VALVIR 450, please consult your health care provider for advice.

If any of the following happens, stop taking / using VALVIR 450 and tell your doctor immediately or go to the casualty department at your nearest hospital:

Allergic reactions

Up to 1 in every 1,000 people may have a sudden and severe allergic reaction to valganciclovir (anaphylactic shock). STOP taking VALVIR 450 and go to the accident and emergency department at your nearest hospital if you experience any of the following:

- a raised, itchy skin rash (hives)
- sudden swelling of the throat, face, lips and mouth which may cause difficulty swallowing or breathing
- sudden swelling of the hands, feet or ankles.

These are all very serious side effects. If you have them, you may have had a serious reaction to VALVIR 450**.** You may need urgent medical attention or hospitalisation

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects – your doctor may tell you to stop taking VALVIR 450 and you may need urgent medical treatment:

Frequent side effects:

- low white blood cell counts – with signs of infection such as sore throat, mouth ulcers or a fever
- low red blood cell counts – signs include feeling short of breath or tired, palpitations or pale skin
- blood infection (sepsis) – signs include fever, chills, palpitations, confusion and slurred speech
- low level of platelets – signs include bleeding or bruising more easily than usual, blood in urine or stools or bleeding from gums, the bleeding could be severe

- severely low blood cell count
- pancreatitis – signs are severe stomach pain which spreads into your back
- fits

Less Frequent side effects:

- failure of the bone marrow to produce blood cells
- hallucinations – hearing or seeing things that are not real
- abnormal thoughts or feelings, losing contact with reality
- failure of kidney function

Other side effects

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

Frequent side effects:

- thrush and oral thrush
- upper respiratory tract infection (e.g. sinusitis, tonsillitis)
- loss of appetite
- headache
- cough
- feeling short of breath
- diarrhoea
- feeling or being sick
- abdominal pain
- eczema
- feeling tired
- fever.
- influenza
- urine infection – signs include fever, passing urine more often, pain when passing urine
- infection of the skin and the tissues under the skin

- mild allergic reaction – the signs may include red, itchy skin
- weight loss
- feeling depressed, anxious or confused
- trouble sleeping
- hands or feet feeling weak or numb, which may affect your balance
- changes to your sense of touch, tingling, tickling, pricking or burning feeling
- changes to the way things taste
- chills
- eye inflammation (conjunctivitis), eye pain or sight problems
- ear pain
- low blood pressure, which may make you feel dizzy or faint
- constipation, wind, indigestion, stomach pain, swelling of the abdomen
- mouth ulcers
- abnormal results of liver and kidney laboratory tests
- night sweats
- itching, rash
- hair loss
- back pain, muscle or joint pain, muscle spasms
- feeling dizzy, weak or generally unwell

Less Frequent side effects:

- feeling agitated
- tremor, shaking
- deafness
- uneven heartbeat
- hives, dry skin
- blood in urine
- infertility in men – see ‘Fertility’ section

- chest pain

Separation of the inner lining of the eye (detached retina) has only happened in AIDS patients treated with VALVIR 450 for CMV infection.

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://www.sahpra.org.za/Publications/Index/8 or drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of VALVIR 450.

5. HOW TO STORE VALVIR 450

Store all medicines out of reach of children.

Store at or below 25 °C.

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 system (e.g. toilets).

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What VALVIR 450 contains

The active substance is 450 mg of valganciclovir, present as 496.3 mg of valganciclovir hydrochloride.

The other ingredients are:

Tablet core: Crosprovidone, microcrystalline cellulose, povidone, stearic acid

Tablet coating: Hypromellose, iron oxide, macrogol, titanium dioxide

What VALVIR 450 looks like and contents of the pack:

What VALVIR 450 looks like

VALVIR 450 is a pink coloured, capsule shaped, biconvex film coated tablets plain on both sides.

Contents of the pack

HDPE Container: One bottle containing 60 film-coated tablets of VALVIR 450 packed in a white opaque high-density polyethylene (HDPE) bottle with a 38 mm child resistant polypropylene white opaque cap (with liner).

Blister pack: 6 x 10 film-coated tablets of VALVIR 450 packed in 0,2 mm PVC/ 90 GSM PVDC coated clear transparent film and 0,025 mm Aluminium foil with NC coating 6-8 GSM VMCH.

Holder of Certificate of Registration

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