

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

OLCICAN 450 MG (FILM-COATED TABLETS)

Valganciclovir

Read all of this leaflet carefully before you start taking OLCICAN 450 MG

- 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.
- OLCICAN 450 MG 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 OLCICAN 450 MG is and what it is used for
2. What you need to know before you take OLCICAN 450 MG
3. How to take OLCICAN 450 MG
4. Possible side effects
5. How to store OLCICAN 450 MG
6. Contents of the pack and other information

1. What OLCICAN 450 MG is and what it is used for

The active ingredient in OLCICAN 450 MG is valganciclovir. OLCICAN 450 MG belongs to a group of medicines, which work directly to prevent the growth of viruses. In the body 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. OLCICAN 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-infections in adults who are not infected with CMV and who have received an organ transplant from somebody who was infected by CMV.

2. What you need to know before you take OLCICAN 450 MG

Do not take OLCICAN 450 MG:

- If you are hypersensitive (allergic) to valganciclovir, ganciclovir, aciclovir, valaciclovir or to any of the other ingredients of OLCICAN 450 MG.
- If you are breastfeeding.

Warnings and precautions

Take special care with OLCICAN 450 MG:

- Ganciclovir is similar to aciclovir and penciclovir, so patients allergic to either of those should be cautiously prescribed OLCICAN 450 MG which contains valganciclovir.
- It is extremely important that both men and women of child-bearing age use effective contraception during treatment with OLCICAN 450 MG. If you need advice on contraception, ask your doctor before you start to take OLCICAN 450 MG. Men should use condoms while taking OLCICAN 450 MG and should continue to use condoms for 90 days after treatment has finished.
- In animal studies, ganciclovir showed properties that could cause genetic mutations, birth defects, cancer, and reduced fertility. Therefore, valganciclovir should be considered a potential cause of birth defects and cancers in humans.
- OLCICAN 450 MG should be used carefully in patients with existing low blood cell counts, those with a history of blood-related issues from medications, and in patients undergoing radiotherapy.
- If you have (or have recently had) low numbers of white blood cells, red blood cells or platelets (small cells involved in blood clotting) in your blood, your doctor will perform blood tests before you start taking OLCICAN 450 MG and more tests will be done while you are taking OLCICAN 450 MG.
- Excessive exposure to ganciclovir can lead to serious, potentially life-threatening side effects. It's important to closely follow dosage guidelines when starting treatment, transitioning from induction to maintenance therapy, and when switching from oral ganciclovir to valganciclovir.
- If you are currently taking ganciclovir capsules and your doctor wants you to switch to OLCICAN 450 MG, it is important that you do not take more than the dose prescribed by your doctor or you could risk an

overdose.

- If you have problems 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 on kidney dialysis or receiving radiotherapy, OLCICAN 450 MG is not suitable for you.

Children

Safety and efficacy for the use of OLCICAN 450 MG in children are limited.

Other medicines and OLCICAN 450 MG

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

Please inform your health care provider if you are currently taking any of the following medicines listed below:

- Imipenem-cilastatin (an antibiotic). Taking this with OLCICAN 450 MG can cause convulsions (fits).
- Probenecid (a medicine for the treatment of gout). Taking probenecid and OLCICAN 450 MG at the same time could increase the amount of ganciclovir in your blood.
- Zidovudine, didanosine, zalcitabine, stavudine or other medicines used in the treatment of HIV/AIDS. Your doctor may reduce the dose of didanosine that you need to take.
- Trimethoprim with or without sulphonamides, pentamidine, flucytosine, amphotericin B and dapsone taken for the treatment of infections.
- Adriamycin, vincristine, vinblastine and hydroxyurea used in the treatment of cancer.
- Mycophenolate mofetil, a medicine that is used in patients who have received an organ transplant.

OLCICAN 450 MG with food and drink

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

Pregnancy, breastfeeding and fertility

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 OLCICAN 450 MG.

Pregnancy

You should not take OLCICAN 450 MG if you are pregnant unless your doctor recommends it. Taking OLCICAN 450 MG when you are pregnant could harm your unborn baby.

Breastfeeding

You must not take OLCICAN 450 MG if you are breastfeeding. If your doctor wants you to begin treatment with OLCICAN 450 MG you must stop breastfeeding before you start to take your tablets.

Fertility

It is also extremely important that both men and women of childbearing age use effective contraception during treatment with OLCICAN 450 MG. Women of childbearing age must use effective contraception when taking OLCICAN 450 MG and for at least 30 days after treatment has finished. Men whose partners could become pregnant should use condoms while taking OLCICAN 450 MG and should continue to use condoms for 90 days after treatment has finished.

Driving and using machines

It is not always possible to predict to what extent OLCICAN 450 MG 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 OLCICAN 450 MG affects them.

If you feel dizzy, sleepy or confused while taking OLCICAN 450 MG, do not drive or operate machinery. Other side effects that can occur with OLCICAN 450 MG and may cause problems if you drive or operate machinery are fits and loss of co-ordination.

3. How to take OLCICAN 450 MG

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

Always take OLCICAN 450 MG 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.

Adults

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

The usual dose OLCICAN 450 MG 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)

Following induction 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 OLCICAN 450 MG. If the inflammation of the retina of your eye 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.

Prevention of CMV disease in transplant patients

You should start to take OLCICAN 450 MG 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 tablets for 200 days.

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. If you are currently on kidney dialysis or receiving radiotherapy, OLCICAN 450 MG should not be used.

Elderly patients

OLCICAN 450 MG has not been studied in elderly patients.

Children

Safety and efficacy of OLCICAN 450 MG have not been established in children.

Your doctor will tell you how long your treatment with OLCICAN 450 MG will last. Do not stop your treatment with OLCICAN 450 MG unless your doctor tells you to. If you have the impression that the effect of OLCICAN 450 MG is too strong or too weak, tell your doctor or pharmacist.

If you take more OLCICAN 450 MG than you should

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

Contact your doctor or hospital immediately if you have taken or think you have taken more OLCICAN 450 MG than you should. Taking too much OLCICAN 450 MG can cause serious side effects, particularly affecting your blood or kidneys. You may need hospital treatment.

If you forget to take OLCICAN 450 MG

It is important that you continue to take your medicine according to the instructions on the label and that you do not miss any doses. However, if you forget to take a dose, take it as soon as you remember (unless it is nearly time for your next dose, in which case leave out the missed dose). Do not take a double dose to make up for forgotten individual doses.

If you stop taking OLCICAN 450 MG

Do not stop your treatment with OLCICAN 450 MG unless your doctor tells you to.

4. Possible side effects

OLCICAN 450 MG can have side effects.

Although OLCICAN 450 MG can help fight CMV infection, it can have some serious side effects. Your doctor

may advise stopping your treatment either temporarily or permanently depending on your condition.

Not all side effects reported for OLCICAN 450 MG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking OLCICAN 450 MG, please inform your health care provider for advice.

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

- 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.
- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Signs of infection such as sore throat, mouth ulcers or a fever due to low white blood cell counts.
- Feeling short of breath or tired, palpitations or pale skin due to low red blood cell counts.
- Fever, chills, palpitations, confusion and slurred speech due to blood infection (sepsis).
- Bleeding or bruising more easily than usual, blood in urine or stools or bleeding from gums, the bleeding could be severe due to low level of platelets.
- Severe stomach pain which spreads into your back due to inflammation of the pancreas (pancreatitis).
- Fits.
- Hearing or seeing things that are not real (hallucinations).
- Decrease in urine output, fluid retention causing swelling of the legs, ankles and feet (kidney failure).

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

The side effects that have occurred during treatment with valganciclovir or ganciclovir are given below. Tell your doctor if you notice any of the following:

Frequent side effects:

- Diarrhoea.
- Headache, difficulty sleeping (insomnia), strange tastes (dysgeusia), becoming less sensitive to touch (hypoesthesia), prickly or tingling skin (paraesthesia), loss of feeling in the hands or feet (peripheral neuropathy), dizziness, (convulsions) and seizure.
- Eye pain, swelling within the eye (oedema), separation of the back of the eye (detached retina) and seeing floaters.
- Earache.
- Coughing.
- Feeling and being sick, stomach pain, constipation, wind, indigestion (dyspepsia) and difficulty swallowing (dysphagia).
- Inflamed skin (dermatitis), itching (pruritus), rash and sweating at night.
- Back pain, pain in the muscles (myalgia) or joints (arthralgia), stiff muscles (rigor) and muscle cramps.
- Fungal infection in the mouth (oral candidiasis), infections caused by bacteria or viruses in the blood, inflammation of cellular tissue (cellulitis) and inflammation or infection of the kidneys or bladder.
- Upper respiratory tract infection, influenza.
- A rise in some liver enzymes, which will only be seen during blood tests.
- Changes to the normal working of the kidneys
- Loss of appetite (anorexia) and weight loss
- Tiredness, fever, pain, chest pain, loss of energy (asthenia), chills and generally feeling unwell (malaise).
- Depression, feeling anxious, confused and having unusual thoughts.

Less frequent side effects:

- Changes to the normal heartbeat (dysrhythmia).
- Low blood pressure (hypotension), which can cause you to feel lightheaded or faint
- A decrease in the production of blood cells in the bone marrow.

- Shaking or trembling (tremor).
- Red, swollen eyes (conjunctivitis) and abnormal vision.
- Deafness.
- Swollen stomach, mouth ulcers and inflammation of the pancreas (pancreatitis) where you may notice severe pain in the stomach and back.
- Hair loss (alopecia), itchy rash or swellings (urticaria) and dry skin.
- Blood in the urine (haematuria) and kidney failure.
- A rise in the liver enzyme called alanine aminotransferase (which will only be seen during blood tests).
- Infertility in men.
- Having unusual changes in mood and behaviour, losing contact with reality such as hearing voices or seeing things that are not there and feeling agitated.
- Failure of the production of all types of blood cells (red blood cells, white blood cells and platelets) in the bone marrow.
- Severe reduction in neutrophils.
- over-than-normal level of granulocytes (a type of white blood cell, including neutrophils)

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

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of OLCICAN 450 MG.

5. How to store OLCICAN 450 MG

Store all medicines out of sight and reach of children.

Store at or below 25 °C (room temperature).

Do not break or crush the tablets. Avoid contact of broken or crushed tablets with skin or mucous membranes.

Do not take OLCICAN 450 MG after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

Return all unused medicines 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 OLCICAN 450 MG contains

The active substance is valganciclovir. Each film-coated tablet contains 496,286 mg of valganciclovir hydrochloride equivalent to 450 mg of valganciclovir.

The other ingredients are:

Tablet core

Microcrystalline cellulose, Povidone (K 30), Crospovidone, Stearic Acid 50

Coating medium (Pink)

Hypromellose Titanium dioxide (E171), Macrogol 400, Red Iron Oxide (E172), Polysorbate 80.

What OLCICAN 450 MG looks like

OLCICAN 450 MG tablets are pink oval film-coated tablets embossed with "450" on one side.

OLCICAN 450 MG tablets are packed in bottles containing 60 film-coated tablets.

Holder of Certificate of Registration

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