

Applicant: Aurogen South Africa (Pty) Ltd

Product Name: ROLIXIRD 450 MG

Dosage form and strength: Tablet, Each film coated tablet contains 496.36 mg of Valganciclovir Hydrochloride equivalent to 450 mg of Valganciclovir.

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SCHEDULING STATUS

S4

PATIENT INFORMATION LEAFLET

ROLIXIRD 450 MG (450 mg) film coated tablet

Valganciclovir Hydrochloride

(Sugar-free)

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

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

What ROLIXIRD 450 MG is and what it is used for

ROLIXIRD 450 MG is indicated for the treatment of cytomegalovirus (CMV) retinitis in acquired immunodeficiency syndrome (AIDS) patients.

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In the prevention of CMV disease in solid organ transplant patients at risk. Valganciclovir is quickly changed in your body to release Ganciclovir, Ganciclovir prevents the growth and the increase in numbers of a virus called Cytomegalovirus (CMV).

1. What you need to know before you take ROLIXIRD 450 MG

Do not take ROLIXIRD 450 MG:

- If you have ever had an allergic reaction to valganciclovir, or to ganciclovir, or to any of the other ingredients of **ROLIXIRD 450 MG**.
- If you have ever had an allergic reaction to aciclovir or valaciclovir.
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Take special care with ROLIXIRD 450 MG

- 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 **ROLIXIRD 450 MG** and more tests will be done while you are taking **ROLIXIRD 450 MG**.
- 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 haemodialysis or receiving radiotherapy. **ROLIXIRD 450 MG** film-coated tablets are not suitable for people on haemodialysis.
- If you are currently taking ganciclovir capsules and your doctor wants you to switch to **ROLIXIRD 450 MG**. It is important that you do not take more than the dose prescribed by your doctor or you could risk an overdose.
- Safety and efficacy - studies of **ROLIXIRD 450 MG** use in children are limited.

Taking other medicines with ROLIXIRD 450 MG:

Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicines). See Do not take ROLIXIRD 450 MG.

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Special care is needed when some other medicines are taken with **ROLIXIRD 450 MG**, Make sure that you tell your doctor about all the medicines that you are taking before you take **ROLIXIRD 450 MG**, including all medicines that have been prescribed for you and any medicines that you have bought without a prescription.

Your doctor may still advise you to take **ROLIXIRD 450 MG** but may ask to see you more often during treatment and it may be necessary to check your blood more often if you are taking the medicines listed below. Taking **ROLIXIRD 450 MG** with these medicines may increase the number and severity of any side effects.

Tell your doctor if you are taking or using any of the following medicines:

If you take **Ganciclovir** Interactions will be expected for **ROLIXIRD 450 MG**.

If you take **Imipenem-cilastatin**. There may be an increased risk of fits when this antibiotic is taken with **ROLIXIRD 450 MG**.

If you take **Trimethoprim** with or without sulphonamides, pentamidine, flucytosine, amphotericin B and dapsone taken for the treatment of infections.

If you take **Adriamycin, vincristine, vinblastine and hydroxyurea** used in the treatment of cancer.

If you take **Zidovudine, didanosine, zalcitabine, stavudine** or other medicines used in the treatment of HIV. Your doctor may reduce the dose of didanosine that you need to take.

If you take **Probenecid** taken for the treatment of gout may increase your blood levels of ganciclovir.

If you take **Mycophenolate mofetil**, a medicine that is used in patients who have received an organ transplant.

If you take **Cidovir, foscarnet, or nucleoside analogues** used against viral infections.

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Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before ROLIXIRD 450 MG is administered to you.

ROLIXIRD 450 MG is not usually given to pregnant woman because it is possible that this could lead to the loss of the baby or to the birth of a malformed baby or to problems in the baby after birth.

Your doctor will only advise you to take **ROLIXIRD 450 MG** if it is clearly needed and only after discussing the risks to the unborn baby with you. If you have any questions, ask your doctor.

It is also important that both men and women of child-bearing age use effective contraception during treatment with ROLIXIRD 450 MG. If you need advice on contraception, ask your doctor before you start to take **ROLIXIRD 450 MG**. Men should use condoms while taking **ROLIXIRD 450 MG** and should continue to use condoms for 90 days after treatment has finished.

Breastfeeding:

ROLIXIRD 450 MG must not be used if you are breastfeeding. The active ingredient, ganciclovir, may pass into the milk and may harm your baby.

Effects on fertility: No human data on the effect of valganciclovir on fertility are available.

Driving and using machines

No studies on the effects on ability to drive and use machines have been performed.

Adverse reactions such as seizures, dizziness, and confusion have been reported with the use of **ROLIXIRD 450 MG** /or ganciclovir. If they occur, such effects may affect tasks requiring alertness, including the patient's ability to drive and operate machinery.

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Important information about some of the ingredients of ROLIXIRD 450 MG

ROLIXIRD 450 MG is Sugar-free.

2. How to take ROLIXIRD 450 MG

Do not share medicines prescribed for you with any other person. Always take ROLIXIRD 450 MG exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will tell you how long your treatment with ROLIXIRD 450 MG will last.

ROLIXIRD 450 MG should be taken with food. If you are unable to eat for any reason, you should still take the dose when it is due.

ROLIXIRD 450 MG tablets should be handled with care and should not be broken or crushed. You should swallow them whole and with food whenever possible.

If you do accidentally get the Valganciclovir hydrochloride on your skin, eyes or touch damaged tablets, wash the area thoroughly with soap and water.

Your doctor will prescribe an appropriate dose according to your condition.

It is VERY IMPORTANT that you follow these special dose instructions from your doctor.

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

Effects when treatment with ROLIXIRD 450 MG 450mg is stopped:

You must not stop taking **ROLIXIRD 450 MG** unless your doctor tells you to. If you have any further questions on the use of **ROLIXIRD 450 MG**, ask your doctor or pharmacist.

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Taking ROLIXIRD 450 MG with food and drink

ROLIXIRD 450 MG should be taken with food.

If you take more ROLIXIRD 450 MG than you should

In the event of over dosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of ROLIXIRD 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 do miss a dose, take it as soon as you remember and take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

3. Possible side effects

ROLIXIRD 450 MG can have side effects.

Not all side effects reported for ROLIXIRD 450 MG are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ROLIXIRD 450 MG, please consult your doctor, pharmacist or other healthcare professional for advice.

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

In adults are neutropenia, anaemia and diarrhoea.

These are all very serious side effects. If you have them, you may have had a serious reaction to **ROLIXIRD 450 MG**. 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:

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Allergic reactions Infrequently, people may have a sudden and severe allergic reaction

(anaphylactic shock) to **ROLIXIRD 450 MG** stop taking and go to the nearest hospital emergency room if you experience any of the following:

- Hives (a raised itchy skin),
- 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 frequent serious side effects. You may need urgent medical attention.

- Candida infections including oral candidiasis (Infections: fungal infection in the mouth),
- Upper respiratory tract infection,
- Neutropenia (a reduction in the number of white blood cells in the blood, which will make you more likely to get infections),
- Anaemia (a reduction in the pigment in the blood that carries oxygen) which can cause tiredness and breathlessness when you exercise,
- Decreased appetite,
- Headache,
- Cough,
- Dyspnoea (feeling short of breath or having trouble breathing),
- Diarrhoea,
- Nausea,
- Vomiting,
- Abdominal pain,
- Dermatitis (inflamed skin),
- Pyrexia (abnormal elevation body temperature),
- Fatigue (tiredness),

Tell your doctor if you notice any of the following:

Frequent side effects:

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- Sepsis (infections caused by bacteria or viruses in the blood),
- Influenza (flu),
- Urinary tract infection,
- Cellulitis (inflammation of cellular tissue),
- Thrombocytopenia (a reduction in the number of platelets in the blood),
- Leukopenia (a reduction in the number of leucocytes) blood cells that fight infection in the blood,
- Pancytopenia (a reduction in several types of blood cells at the same time Hypersensitivity),
- Weight decreased,
- Depression,
- Confusional state,
- Anxiety (restlessness),
- Insomnia (Inability to sleep),
- Neuropathy peripheral,
- Dizziness,
- Paraesthesia (prickly or tingling skin),
- Hypoaesthesia (becoming less sensitive to touch),
- Seizure (convulsions),
- Dysgeusia (taste disturbance),
- Visual impairment,
- Retinal detachment, (Vitreous floaters) spots in the vision,
- Eye pain,
- Conjunctivitis (swollen eyes),
- Macular oedema (build-up of fluid in the macula),
- Ear pain,
- Hypotension (low blood pressure),
- Dyspepsia (heartburn),
- Flatulence,

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- Abdominal pain upper,
- Constipation,
- Mouth ulceration,
- Dysphagia (difficulty swallowing),
- Abdominal distention,
- Pancreatitis (inflammation of the pancreas),
- Blood alkaline phosphatase increased,
- Hepatic function abnormal,
- Aspartate aminotransferase increased
- Alanine aminotransferase increased
- Night sweats,
- Pruritus (itching),
- Rash,
- Alopecia (hair loss),
- Back pain,
- Myalgia (pain in the muscles),
- Arthralgia (pain in the joints),
- muscle cramps,
- Renal impairment,
- Creatinine clearance renal decreased,
- Blood creatinine increased,
- Renal failure,
- Pain,
- Chills,
- Malaise (generally feeling unwell),
- Asthenia (loss of energy),

Less frequent side effects:

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- Bone marrow failure,
- Agitation,
- Psychotic disorder,
- Thinking abnormal,
- Hallucinations,
- Tremor (shaking or trembling),
- Deafness,
- Dysrhythmias (irregular heartbeat),
- Dry skin,
- Urticaria (itchy rash or swellings),
- Haematuria (blood in the urine),
- Infertility male,
- Chest pain,
- Aplastic anaemia (body stops producing enough new blood cells),
- Agranulocytosis (deficiency of granulocytes in the blood),
- Granulocytopenia (a marked decrease in the number of granulocytes),
- Anaphylactic reaction,

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via

https://www.sahpra.org.za/documents/86422f1b6.04_ARF1_Jul16_v4.pdf. By reporting side effects, you can help provide more information on the safety of this medicine.

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4. How to store ROLIXIRD 450 MG

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

5. Contents of the pack and other information

What ROLIXIRD 450 MG contains

The active substance is Valganciclovir Hydrochloride

Each film coated tablet contains 496.36 mg of Valganciclovir hydrochloride equivalent to 450 mg of valganciclovir.

The other ingredients of **ROLIXIRD 450 MG** are cellulose microcrystalline (PH 101), cellulose microcrystalline (PH 102), Crospovidone, Povidone, magnesium stearate, Opadry pink YS-1-14519A and purified water.

ROLIXIRD 450 MG Sugar-free.

What ROLIXIRD 450 MG looks like and contents of the pack

ROLIXIRD 450 MG 450 mg

Pink colored, oval shaped biconvex, film-coated tablets, debossed with 'H' on one side and '96' on other side.

60 tablets are packed in a Blister strips of 25 µ Polyamide/ 45 µ Aluminium foil/ 60 µ PVC film.

Pack sizes: 10 film coated tablets per blister. One box contains 10 x 6 blisters.

60 tablets are packed in white opaque round HDPE container closed with a white opaque polypropylene continuous thread closures with wad having induction sealing liner.

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Pack sizes: 60's - One HDPE container contains 60 tablets.

HDPE bottle and blister packs are enclosed in an outer carton box.

**NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE
CERTIFICATE OF REGISTRATION**

AUROGEN SA (Pty) Ltd

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Registration number

49/20.2.8/0106