

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS****S4****GANCLO powder for concentrate for solution for infusion****Ganciclovir****Sugar free****Read all of this leaflet carefully before you start receiving GANCLO**

- 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.
- GANCLO 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 GANCLO is and what it is used for
2. What you need to know before you receive GANCLO
3. How to receive GANCLO
4. Possible side effects
5. How to store GANCLO
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1. What GANCLO is and what it is used for

Cytomegalovirus (CMV) is a virus that can infect any part of the body, including the retina of the eye, where it causes inflammation (CMV retinitis), and problems with eyesight.

GANCLO contains the active substance ganciclovir. Ganciclovir is an antiviral medicine and it acts by stopping the CMV virus reproducing and invading healthy cells. This may slow down the progression of your retinitis.

GANCLO for intravenous infusion is used for the prevention or treatment of cytomegalovirus (CMV) infections in patients whose immune system is not functioning fully because of the effect of other infections or medicines.

2. What you need to know before you receive GANCLO

Do not receive GANCLO:

- If you are hypersensitive (allergic) to ganciclovir, valganciclovir or any of the other ingredients of GANCLO (listed in section 6).
- If you are allergic to aciclovir, valaciclovir, penciclovir or famciclovir – these are other medicines used for viral infections.
- If you are pregnant or breastfeeding.
- If you have very low levels of certain proteins (haemoglobin or platelets) or cells (white blood cells) in your blood.
- If you are receiving treatment that reduces your bone marrow activity.

Warnings and precautions

Take special care with GANCLO:

- If you have ever had an allergic reaction to aciclovir or penciclovir (or their prodrugs valaciclovir or famciclovir). These are medicines used for viral infections.

- If you have low numbers of certain types of blood cells (known as white blood cells and platelets). This will be detected in a blood test performed by your doctor.
- If you are already taking a medicine that contains zidovudine. Taking this together with GANCLO may lead to a severe reduction in the number of white blood cells or red blood cells in your blood.
- If you had problems with your blood cell counts caused by medicines you have used in the past.
- Make sure your doctor knows if you are taking the following medicines: probenecid, imipenem/cilastatin, didanosine, mycophenolate, dapsone, pentamidine, flucytosine, vincristine, vinblastine, adriamycin, anticancer/antiviral medicines.
- If you have any kidney problems. Your doctor may need to prescribe a reduced dose for you and may need to check your blood frequently during treatment.
- It is very important that both men and women of child bearing/procreation potential use effective contraception during treatment with GANCLO; men should continue to use condoms for 90 days following treatment (see POSSIBLE SIDE EFFECTS).

While you are using GANCLO your doctor will do regular blood tests. This is to check the dose you are having is right for you. For the first 2 weeks these blood tests will be done often. After that the tests will be done less often.

Children and adolescents

Safety and efficacy of GANCLO use in children and adolescents has not been established.

Other medicines and GANCLO

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

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Imipenem/cilastatin – used for bacterial infections. Taking this with GANCLO can cause convulsions (fits).
- Pentamidine – used for parasite or lung infections. Your doctor may need to adjust the dose of GANCLO in order to prevent toxicity, especially if you have kidney problems.
- Flucytosine, amphotericin B – used for fungal infections. Your doctor may need to adjust the dose of GANCLO in order to prevent toxicity, especially if you have kidney problems.
- Trimethoprim, trimethoprim/sulfamethoxazole, dapsone – used for bacterial infections. Your doctor may need to adjust the dose of GANCLO in order to prevent toxicity, especially if you have kidney problems.
- Probenecid – used for gout. Taking probenecid and GANCLO at the same time could increase the amount of ganciclovir in your blood.
- Mycophenolate mofetil, ciclosporin, tacrolimus – used after an organ transplant. Your doctor may need to adjust the dose of GANCLO in order to prevent toxicity, especially if you have kidney problems.
- Vincristine, vinblastine, doxorubicin – used for cancer. Your doctor may need to adjust the dose of GANCLO in order to prevent toxicity, especially if you have kidney problems.
- Hydroxyurea – used for a problem called polycythemia, sickle cell disease and cancer. Your doctor may need to adjust the dose of GANCLO in order to prevent toxicity, especially if you have kidney problems.

- Didanosine, stavudine, zidovudine, tenofovir or any other medicines used for HIV. Taking this together with GANCLO may lead to a severe reduction in the number of white blood cells or red blood cells in your blood.
- Adefovir or any other medicines used to treat Hepatitis B. Your doctor may need to adjust the dose of GANCLO in order to prevent toxicity, especially if you have kidney problems.

Pregnancy and breastfeeding

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 receiving this medicine

GANCLO should not be used by pregnant women.

Do not receive GANCLO if you are breastfeeding your baby.

Contraception

You should not become pregnant while receiving this medicine. This is because it may affect the unborn baby.

Women: If you are a woman who could get pregnant – use contraception while you are receiving GANCLO. Also do this for at least 30 days after GANCLO has been stopped.

Men: If you are a man whose female partner could get pregnant – use a barrier method of contraception (such as condoms) while you are receiving GANCLO. Also do this for at least 90 days after GANCLO has been stopped.

Driving and using machines

It is not always possible to predict to what extent GANCLO 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 GANCLO affects them.

If you feel dizzy, tired, shaky or confused while receiving GANCLO, do not drive or operate machinery.

3. How to receive GANCLO

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

You will not be expected to give yourself GANCLO. It will be given to you by a person who is qualified to do so.

GANCLO should always be used as directed by your doctor. The doctor will ensure that it is correctly made into a solution before use.

The solution is usually administered by your doctor or nurse into a vein via a plastic tube. This usually takes at least one hour.

The initial dose is usually 5 milligrams (mg) for every kilogram (kg) that you weigh.

The dose may be administered every 12 hours for 7 – 21 days.

After this, the same dose may be given once a day, every day, for 7 days a week.

Otherwise, 6 mg for every kg that you weigh (6 mg/kg) may be given once a day for 5 days each week.

If your kidney function is less than normal, your doctor may prescribe a different dose.

To assess your treatment, you may need to have regular blood tests.

If you receive more GANCLO than you should

Since a health care provider will administer GANCLO, he/ she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive GANCLO

Since a health care provider will administer GANCLO, it is unlikely that the dose will be missed.

4. Possible side effects

GANCLO can have side effects.

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

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

- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to GANCLO. 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:

Frequent

- 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 (this is detected by blood tests),
- pancreatitis – signs are severe stomach pain which spreads into your back,
- fits.

Less frequent

- 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.

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

Tell your doctor if you notice any of the following:

Frequent

- 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,
- problems swallowing,
- 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,
- a skin reaction where the medicine was injected – such as inflammation, pain and swelling.

Less frequent

- feeling agitated,
- tremor, shaking,
- deafness,
- uneven heartbeat,
- hives, dry skin,
- blood in urine,
- infertility in men,
- chest pain.

Frequency unknown

- allergic 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 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 GANCLO.

5. How to store GANCLO

Store all medicines out of reach of children.

- Store at or below 25 °C.

After reconstitution: Chemical and physical in-use stability has been demonstrated for the reconstituted medicine for 12 hours at 25 °C after dissolving with water for injections. Do not refrigerate or freeze.

After dilution: Chemical and physical in-use stability in 4 diluents (0,9 % sodium chloride injection, 5 % glucose injection, Ringer's injection, and Lactated Ringer's injection) and the reconstituted solution have been demonstrated for 4 hours at or below 25 °C and 24 hours at 2 – 8°C (do not freeze).

Do not use after the expiry date stated on the label or 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 GANCLO contains

- The active substance is ganciclovir sodium.

Each vial of GANCLO sterile powder contains 543 mg of sterile freeze dried ganciclovir sodium equivalent to 500 mg ganciclovir.

- The other ingredients are hydrochloric acid, sodium hydroxide and water for injection.

What GANCLO looks like and contents of the pack

GANCLO is a white porous cake or powder.

GANCLO is packed in a 10 ml Type 1 glass vial with a 20 mm bromobutyl rubber stopper and a 20 mm aluminium-plastic overseal.

Vials of GANCLO are supplied in packs of 1 or 10 in an outer cardboard box. Not all pack sizes may be marketed.

Holder of Certificate of Registration

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To follow

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Access to the corresponding Professional Information

www.kahmahealthcaregroup.co.za