

Package leaflet: Information for the user

Ganciclovir Bioglan 500 mg powder for concentrate for solution for infusion

Ganciclovir

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you use Ganciclovir Bioglan
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1. What Ganciclovir Bioglan is and what it is used for

What Ganciclovir Bioglan is

Ganciclovir Bioglan contains the active substance ganciclovir. This belongs to a group called antiviral medicines.

What Ganciclovir Bioglan is used for

Ganciclovir Bioglan is used to treat diseases caused by a virus called cytomegalovirus (CMV) in adults and adolescents patients 12 years and old who have a weak immune system. It is also used to prevent CMV infection after an organ transplant or during chemotherapy in adults and children from birth.

- The virus can affect any part of the body. This includes the retina at the back of the eye – this means the virus can cause problems with eye sight.
- The virus can affect anyone, but it is a particular problem in people with a weak immune system. In these people the CMV virus can lead to a serious disease. A weak immune system may be caused by other diseases (such as AIDS) or by medicines (such as chemotherapy or immunosuppressants).

2. What you need to know before you use Ganciclovir Bioglan

Do not use Ganciclovir Bioglan if:

- you are allergic to ganciclovir, valganciclovir or any of the other ingredients of this medicine (listed in section 6).
- you are breast-feeding (see Breast-feeding subsection).

Do not use Ganciclovir Bioglan if any of the above apply to you. If you are not sure, talk to your doctor, pharmacist or nurse before using Ganciclovir Bioglan.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ganciclovir Bioglan if:

- you are allergic to aciclovir, valaciclovir, penciclovir or famciclovir – these are other medicines used for viral infections.
- you have low white blood cell, red blood cell or platelet counts – your doctor will do blood tests before you start and during your treatment.
- you have had problems with your blood cell counts caused by medicines in the past.
- you have kidney problems – your doctor will need to give you a lower dose and check your blood cell counts more often during treatment.
- you are having radiotherapy.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before using Ganciclovir Bioglan.

Look out for side effects

Ganciclovir Bioglan can cause some serious side effects that you need to tell your doctor about straight away. Look out for serious side effects listed in Section 4 and tell your doctor if you notice any of these while you are taking Ganciclovir Bioglan– your doctor may tell you to stop taking Ganciclovir Bioglan and you may need urgent medical treatment.

Tests and checks

While you are using Ganciclovir Bioglan 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

There is limited information on how safe or effective Ganciclovir Bioglan is as a treatment for CMV disease in children under 12 years. Babies and infants given Ganciclovir Bioglan for prevention of CMV disease, will undergo regular blood tests.

Other medicines and Ganciclovir Bioglan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines..

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

- imipenem/cilastatin - used for bacterial infections,
- pentamidine – used for parasite or lung infections,
- flucytosine, amphotericin B – used for fungal infections,
- trimethoprim, trimethoprim/sulfamethoxazole, dapsone – used for bacterial infections,
- probenecid – used for gout,
- mycophenolate mofetil, ciclosporin, tacrolimus – used after an organ transplant,
- vincristine, vinblastine, doxorubicin – used for cancer,
- hydroxyurea – used for a problem called polycythemia, sickle cell disease and cancer,
- didanosine, stavudine, zidovudine, tenofovir or any other medicines used for HIV,
- adefovir and any other medicines used to treat Hepatitis B.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Ganciclovir Bioglan.

Pregnancy, breastfeeding and fertility

Pregnancy

Ganciclovir Bioglan should not be used by pregnant women unless the benefits to the mother outweigh the possible risks to the unborn baby.

If you are pregnant or think you might be pregnant, do not use this medicine unless your doctor tells you to. This is because Ganciclovir Bioglan may harm the unborn baby.

Contraception

You should not become pregnant while using 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 using Ganciclovir Bioglan. Also do this for at least 26 weeks after Ganciclovir Bioglan has been stopped.

Men

If you are a man whose female partner could get pregnant – use condoms plus an additional contraceptive method while you are using Ganciclovir Bioglan. Also do this for at least 90 days after Ganciclovir Bioglan has been stopped.

If you or your partner becomes pregnant while using Ganciclovir Bioglan, talk to your doctor straight away.

Breast-feeding

Do not use Ganciclovir Bioglan if you are breast-feeding. If your doctor wants you to start using Ganciclovir Bioglan you must stop breast-feeding before you start using the medicine. This is because Ganciclovir Bioglan may pass into breast milk.

Fertility

Ganciclovir Bioglan may affect fertility. Ganciclovir Bioglan may temporarily or permanently stop men from producing sperm. If you are planning to have a baby, talk to your doctor or pharmacist before using Ganciclovir Bioglan.

Driving and using machines

You may feel sleepy, dizzy, confused or shaky, or you may lose your balance or have fits while using Ganciclovir Bioglan. If this happens, do not drive or use any tools or machines.

Ganciclovir Bioglan contains sodium.

This medicine contains 43 mg of sodium (main component of cooking/table salt) in each 500 mg dose. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Ganciclovir Bioglan

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Using this medicine

Ganciclovir Bioglan will be given to you by a doctor or nurse. It will be given through a tube into your vein. This is called an intravenous infusion and it will usually take one hour.

The dose of Ganciclovir Bioglan varies from one patient to another. Your doctor will work out how much you need. It will depend on:

- your weight (in children their height may also be taken into account),
- your age,
- how well your kidneys are working,
- your blood counts,
- what you are using the medicine for.

How often you will have Ganciclovir Bioglan and how long you keep using it will also vary.

- You will usually start by having one or two infusions every day.
- If you have two infusions a day, this will continue for up to 21 days.
- After that the doctor may prescribe the infusion once a day.

People with kidney or blood problems

If you have any kidney or blood problems your doctor might suggest a smaller dose of Ganciclovir Bioglan and check your blood cell counts more often during treatment.

If you use more Ganciclovir Bioglan than you should

If you think you have been given too much Ganciclovir Bioglan talk to your doctor or go to hospital straight away. You may get the following symptoms if you have too much:

- stomach pain, diarrhoea or being sick
- shaking or fits
- blood in your urine
- kidney or liver problems
- changes in blood cell counts.

If you stop using Ganciclovir Bioglan

Do not stop using Ganciclovir Bioglan without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor ,pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

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 Ganciclovir Bioglan and you may need urgent medical treatment:

Very common: may affect more than 1 in 10 people

- 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.

Common: may affect up to 1 in 10 people

- 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

Uncommon: may affect up to 1 in 100 people

- 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.

Rare: may affect up to 1 in 1,000 people

- severe allergic reaction – the signs may include, red itchy skin, swelling of the throat, face, lips or mouth, difficulty swallowing or breathing.

Tell your doctor straight away if you notice any of the side effects above.

Other side effects

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

Very common: may affect more than 1 in 10 people

- 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.

Common: may affect up to 1 in 10 people

- 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.

Uncommon: may affect up to 1 in 100 people

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

Side effects in children and adolescents

Low blood cell counts are more likely in children, especially babies and infants.

Reporting of side effects

If you get any 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 directly via **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ganciclovir Bioglan

Keep this medicine out of the sight and reach of children.

Unopened vials: This medicinal product does not require any special storage conditions. It should not be used after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

After reconstitution:

Chemical and physical in-use stability has been demonstrated for 12 hours at 25°C. Do not refrigerate or freeze.

After dilution in a compatible infusion solutions:

Chemical and physical in-use stability has been demonstrated for 24 hours at 2 to 8°C.

From a microbiological point of view, unless the method of reconstitution and dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage and conditions are the responsibility of the user.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Ganciclovir Bioglan contains**

The active substance is ganciclovir. One glass vial contains ganciclovir sodium, equivalent to 500 mg of ganciclovir. Following reconstitution of the powder, 1ml of the concentrate for solution contains 50 mg ganciclovir.

What Ganciclovir Bioglan looks like and contents of the pack

Ganciclovir Bioglan is a white to off white lyophilized cake or powder supplied in a single-dose glass vial, with a chlorobutyl rubber stopper and aluminum closure with flip-off plastic cap. Reconstituted solutions of Ganciclovir Bioglan range in colour from colourless to light yellow.

Vials of Ganciclovir Bioglan are supplied in packs of 1 or 5. Not all pack sizes may be marketed.

Marketing Authorisation Holder

To be completed nationally.

Manufacturer

Laboratorio Reig Jofre, S.A.
Gran Capitan 10, 08970
Sant Joan Despí (Barcelona)
Spain

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The following information is intended for healthcare professionals only:

INSTRUCTIONS FOR USE AND HANDLING

Please refer to the Summary of Product Characteristics for full prescribing information.

Method of administration

Caution:

Ganciclovir must be administered by intravenous infusion over 1 hour at a concentration not exceeding 10 mg/mL. Do not administer by rapid or bolus intravenous injection because the resulting excessive plasma levels may increase the toxicity of ganciclovir.

Do not administer by intramuscular or subcutaneous injection because this may result in severe tissue irritation due to the high pH (~11) of ganciclovir solutions.

The recommended dosage, frequency and infusion rates should not be exceeded.

Ganciclovir Bioglan is a powder for solution for infusion. After reconstitution Ganciclovir Bioglan is a colourless to slightly yellowish solution, practically free from visible particles.

The infusion should be given into a vein with adequate blood flow, preferably via a plastic cannula.

Caution should be exercised in the handling of Ganciclovir Bioglan.

Since Ganciclovir Bioglan is considered a potential teratogen and carcinogen in humans, caution should be observed in its handling. Avoid inhalation or direct contact of the powder contained in the vials or direct contact of the reconstituted solution with the skin or mucous membranes. Ganciclovir Bioglan solutions are alkaline (pH ~11). If such contact occurs, wash thoroughly with soap and water, rinse eyes thoroughly with plain water.

Preparation of the reconstituted concentrate

Aseptic technique should be used throughout to reconstitute lyophilised Ganciclovir Bioglan.

1. The flip-off cap should be removed to expose the central portions of the rubber stopper. Draw 10 mL of water for injection into a syringe, then slowly inject through the centre of the rubber stopper into the vial pointing the needle towards the wall of the vial. Do not use bacteriostatic water for injection containing parabens (para-hydroxybenzoates), since these are incompatible with Ganciclovir Bioglan.
2. The vial should be gently swirled in order to ensure complete wetting of the product.
3. The vial should be gently rotated/swirled for some minutes to obtain a clear reconstituted solution.
4. The reconstituted solution should be checked carefully to ensure that the product is in solution and practically free from visible particles prior to dilution with compatible solvent. Reconstituted solutions of Ganciclovir Bioglan range in colour from colourless to light yellow.

Preparation of final diluted solution for infusion

Based on patient weight the appropriate volume should be removed with a syringe from the vial and further diluted into an appropriate infusion solution. Add a volume of 100 mL of diluent to the reconstituted solution. Infusion concentrations greater than 10 mg/mL are not recommended. Sodium chloride, dextrose 5%, Ringer's or lactated Ringer's solutions are determined chemically or physically compatible with Ganciclovir Bioglan.

Ganciclovir Bioglan should not be mixed with other intravenous products.

The diluted solution should then be infused intravenously over 1 hour. Do not administer by intramuscular or subcutaneous injection because this may result in severe tissue irritation due to the high pH (~11) of ganciclovir solution.

Disposal

For single use only. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.