

Package leaflet: Information for the user

Ganciclovir Oresund Pharma 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

1. What Ganciclovir Oresund Pharma is and what it is used for
2. What you need to know before you use Ganciclovir Oresund Pharma
3. How to use Ganciclovir Oresund Pharma
4. Possible side effects
5. How to store Ganciclovir Oresund Pharma
6. Contents of the pack and other information

1. What Ganciclovir Oresund Pharma is and what it is used for

What Ganciclovir Oresund Pharma is

Ganciclovir Oresund Pharma contains the active substance ganciclovir. This belongs to a group called anti-viral medicines.

What Ganciclovir Oresund Pharma is used for

Ganciclovir Oresund Pharma is used to treat diseases caused by a virus called cytomegalovirus (CMV) in adults and adolescent patients 12 years and older 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 eyesight.
- 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 Oresund Pharma

Do not use Ganciclovir Oresund Pharma

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

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Ganciclovir Oresund Pharma 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 Oresund Pharma.

Look out for side effects

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

Tests and checks

While you are using Ganciclovir Oresund Pharma 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 Oresund Pharma is as a treatment for CMV disease in children under 12 years. Babies and infants given Ganciclovir Oresund Pharma for prevention of CMV disease, will undergo regular blood tests.

Other medicines and Ganciclovir Oresund Pharma

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 or 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 Oresund Pharma.

Pregnancy, breast-feeding and fertility

Ganciclovir Oresund Pharma 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 Oresund Pharma 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 Oresund Pharma. Also do this for at least 30 days after Ganciclovir Oresund Pharma 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 using Ganciclovir Oresund Pharma. Also do this for at least 90 days after Ganciclovir Oresund Pharma has been stopped.

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

Breast-feeding

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

Fertility

Ganciclovir Oresund Pharma may affect fertility. Ganciclovir Oresund Pharma 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 Oresund Pharma.

Driving and using machines

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

Ganciclovir Oresund Pharma contains sodium

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

3. How to use Ganciclovir Oresund Pharma

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 Oresund Pharma 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 Oresund Pharma 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 Oresund Pharma 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 Oresund Pharma and check your blood cell counts more often during treatment.

If you use more Ganciclovir Oresund Pharma than you should

If you think you have been given too much Ganciclovir Oresund Pharma 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 Oresund Pharma

Do not stop using Ganciclovir Oresund Pharma 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 Oresund Pharma 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 1000 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 Oresund Pharma

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

Powder:

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

After reconstitution:

After dissolving the powder in the injection vial, the product is stable for 12 hours if stored at room temperature (20-25 °C). Do not refrigerate or freeze.

From a microbiological point of view, the reconstituted solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

After dilution:

When this solution is added to the infusion liquid, the product is stable for 24 hours at 2-8°C. Do not freeze.

From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times 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 Oresund Pharma contains

- The active substance is ganciclovir. Each vial contains 500 mg ganciclovir as ganciclovir sodium. Following reconstitution of the powder, 1 ml solution contains 50 mg ganciclovir.
- The other ingredients are sodium hydroxide and hydrochloric acid.

What Ganciclovir Oresund Pharma looks like and contents of the pack

Ganciclovir Oresund Pharma is a white lyophilised powder for concentrate for solution for infusion in a single-dose glass vial, with a rubber stopper and aluminium closure with flip-off cap.

Reconstituted solutions of ganciclovir range in colour from colourless to light yellow. A pack contains 1 glass vial, 5 glass vials or 10 glass vials of 10 ml. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Øresund Pharma ApS
Orient Plads 1
2150 Nordhavn
Denmark

Manufacturer

Quercus Labo bv
Wijmenstraat 21P
9030 Mariakerke
Belgium

This medicine is authorised in the Member States of the European Economic Area under the following names:

<{Name of the Member State}> <{Name of the medicine}>
<{Name of the Member State}> <{Name of the medicine}>

This leaflet was last revised in 2024-06-10

The following information is intended for healthcare professionals only:

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 Oresund Pharma is a powder for concentrate for solution for infusion. After reconstitution Ganciclovir Oresund Pharma 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 Oresund Pharma.

Since Ganciclovir Oresund Pharma 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 Oresund Pharma 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

The contents of the vial should be prepared for administration in the following manner using aseptic technique:

1. Lyophilized ganciclovir should be reconstituted with 10 ml sterile water for injection by injecting into the vial. Do not use bacteriostatic water for injection containing parabens (para-hydroxybenzoates), since these are incompatible with ganciclovir.
2. Shake the vial for 60 seconds to dissolve the medicinal product. After reconstitution, the vial contains a clear solution and is practically free from visible particles.
3. The reconstituted solution should be inspected for the presence of particles before addition to infusion fluid.
4. Chemical and physical in-use stability of the reconstituted solution in the vial has been demonstrated for 12 hours at 20-25 °C. It should not be frozen.

Preparation of final diluted solution for infusion

Based on the weight of the patient and the therapeutic indication, the appropriate calculated volume should be removed from the vial and added to an acceptable infusion fluid (usually 100 ml) for administration over a period of 1 hour.

The following infusion fluids are determined chemically and physically compatible with ganciclovir: sodium chloride 9 mg/ml, glucose 50 mg/ml, Ringer's solution, lactated Ringer's solution.

Each ganciclovir-containing infusion solution should be used within 24 hours of preparation in order to reduce the risk of bacterial contamination. The remainder of the reconstituted solution in the vial should be discarded after 12 hours.

Disposal

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