

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Ganciclovir 500 mg Powder for Infusion *

Read all of this leaflet carefully before you start taking 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, health care provider or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if the signs of their illness are the same as yours.
- If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. WHAT GANCICLOVIR 500 mg POWDER FOR INFUSION IS AND WHAT IT IS USED FOR

Ganciclovir 500 mg Powder for Infusion contains a medicine called ganciclovir. It belongs to a group of medicines called ‘antivirals’.

Ganciclovir 500 mg Powder for Infusion is used to treat infections caused by a virus called cytomegalovirus (CMV). In people with a poor immune system because of other diseases or medicines (people who are ‘immuno-compromised’), the infection can be severe and cause serious effects.

CMV can infect any part of the body. Infection in the retina of the eye (‘CMV retinitis’) can affect eyesight. In most people with CMV retinitis, Ganciclovir 500 mg Powder for Infusion slows down or prevents the spread of CMV to healthy cells, thereby protecting eyesight from damage.

Ganciclovir 500 mg Powder for Infusion does not cure CMV retinitis, and in some people the retinitis may progress during or after treatment with Ganciclovir 500 mg Powder for Infusion.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN GANCICLOVIR 500 mg POWDER FOR INFUSION

You must not be given Ganciclovir 500 mg Powder for Infusion if:

- you are allergic (hypersensitive) to ganciclovir.
- you are allergic to similar antiviral medicines including valganciclovir, aciclovir and valaciclovir.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

3. HOW GANCICLOVIR 500 mg POWDER FOR INFUSION WILL BE GIVEN

Ganciclovir 500 mg Powder for Infusion will be given to you by a doctor or health care provider through a small tube into one of your veins. It usually takes one hour for the medicine to be given into your vein (called an 'intravenous infusion').

- The dose of Ganciclovir 500 mg Powder for Infusion varies from one patient to another. The usual dose is 5 mg for every kilogram that you weigh (5 mg/kg). However, the dose may need to be reduced according to how well your kidneys are working. The doctor or health care provider will work out how much to give you.
- How often you have Ganciclovir 500 mg Powder for Infusion and how long your treatment continues also varies from one patient to another. You will usually start by having one infusion every 12 hours for up to 21 days. After that you may have one infusion a day.
- Your doctor or health care provider will check how well the medicine is working and you may need to have regular blood tests. If necessary your dose might be changed or your treatment stopped.

If you are given more Ganciclovir 500 mg Powder for Infusion than you should have

- If you are given too much Ganciclovir 500 mg Powder for Infusion your blood test results may change, you may develop problems with your liver or kidneys, and get effects such as stomach pain, being sick, diarrhoea, fits and shaking.
- If you think you have been given too much Ganciclovir 500 mg Powder for Infusion, tell your doctor or health care provider.

If you have any further questions on the use of this medicine, ask your doctor or health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects but not everybody gets them.

Allergic reactions (uncommon, affect fewer than 1 in 100 people)

If you have an allergic reaction, tell a doctor straight away. The signs may include:

- A raised itchy skin rash (hives).
- Difficulty breathing or swallowing caused by sudden swelling of the throat, face, lips and mouth.
- Sudden swelling of the hands, feet and ankles.

Other possible side effects

Very common (affect more than 1 in 10 people)

- Low numbers of one type of white blood cell (called neutrophils)—the signs include infections of the mouth, gums, throat and lungs. Your doctor or health care provider may want you to have blood tests
- Low numbers of red blood cells (anaemia)—the signs include feeling tired, pale skin, palpitations (a fluttering sensation in the heart) and being short of breath
- Difficulty breathing
- Diarrhoea

Common (affect fewer than 1 in 10 people)

- Infections of the blood, skin, urinary tract and mouth. The signs include high temperature (fever), chills, feeling tired, redness and swelling of the skin, pain on passing water and creamy white spots in the mouth.
- Reduction in all types of white blood cells. The signs include infections of the mouth, gums, throat and lungs.

- Reduced number of platelets in your blood. The signs include bruising easily and nose bleeds.
- Reduction in all the types of cells in your blood. The signs include feeling tired, bruising easily, being short of breath and nose bleeds.
- Loss of appetite
- Depression, anxiety, feelings of confusion and abnormal thinking
- Headache
- Difficulty in sleeping
- Changes to the way things taste
- Dizziness
- Fits ('convulsions')
- Changes in your skin sensitivity (such as numbness, pins and needles, burning sensations)
- Changes to your eye-sight, loss of vision or eye pain
- Earache
- Cough
- Feeling or being sick, pain in your stomach, constipation, wind and difficulty swallowing
- Problems with your liver, shown in a blood test
- Skin rashes (including inflammation, redness and blistering), itchiness and sweating at night
- Pain in your back, joints, muscles or chest or muscle cramps
- Problems with your kidneys. This may affect the amount of water (urine) that you pass
- Feeling tired, unwell or weak, high temperature (fever), shivering, weight loss
- A reaction near the vein where Ganciclovir 500 mg Powder for Infusion was given

Uncommon (affect fewer than 1 in 100 people)

- Changes to your bone marrow (which may affect the production of some blood cells)
- Mental disturbance, including feeling agitated and losing contact with reality
- Shaking or trembling that you cannot control
- Infection of the eye (conjunctivitis)
- Deafness.
- Uneven heart beat.
- Low blood pressure—the signs include feeling dizzy or light-headed
- Mouth ulcers, swelling of the abdomen (tummy) and pancreatitis. The signs of pancreatitis include severe pain in the stomach which spreads to your back
- Loss of hair and dry skin
- Serious kidney disease
- Blood in your urine (water)
- Infertility in men. Ganciclovir 500 mg Powder for Infusion may stop sperm production. This can be temporary or permanent.

If any of the side effects become serious or troublesome or if you notice any side effects not listed in this leaflet, tell your doctor or health care provider.

5. HOW GANCICLOVIR 500 mg POWDER FOR INFUSION IS STORED

- Your doctor, health care provider or pharmacist is responsible for storing Ganciclovir 500 mg Powder for Infusion. They are also responsible for the correct disposal of any unused Ganciclovir 500 mg Powder for Infusion.

- Keep out of the reach and sight of children.
- Ganciclovir 500 mg Powder for Infusion must not be stored above 30°C. It should be protected from light.
- Do not use Ganciclovir 500 mg Powder for Infusion after the expiry date printed on the pack.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ganciclovir 500 mg Powder for Infusion contains

The active substance in Ganciclovir 500 mg Powder for Infusion powder for infusion is ganciclovir. Each glass vial contains 500 mg ganciclovir as ganciclovir sodium 543 mg. Sodium content per vial is 46 mg.

There are no other ingredients in Ganciclovir 500 mg Powder for Infusion.

What Ganciclovir 500 mg Powder for Infusion looks like and contents of the pack

Ganciclovir 500 mg Powder for Infusion is a powder, supplied in a glass vial. Before it is given, Ganciclovir 500 mg Powder for Infusion is made into a solution by adding sterile water to the vial. The correct dose is then taken out of the vial and added to the infusion solution to be given to the patient.

Vials of Ganciclovir 500 mg Powder for Infusion are supplied in packs of 10.

Supplier and Manufacturer

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Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal/>.