

## **WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET**

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

[HA515 trade name] †  
Ganciclovir (as sodium)

*The warnings and instructions in this leaflet are intended for the person taking the medicine.  
If you are a parent or carer responsible for giving the medicine to someone else such as a child,  
you will need to apply the instructions accordingly.*

### **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 questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you get any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### **What is in this leaflet**

1. What [HA515 trade name] is and what it is used for
2. What you need to know before you take [HA515 trade name]
3. How to take [HA515 trade name]
4. Possible side effects
5. How to store [HA515 trade name]
6. Contents of the pack and other information

#### **1. What [HA515 trade name] is and what it is used for**

[HA515 trade name] is a medicine used to treat infections caused by a virus called cytomegalovirus (CMV) in people who have a weakened immune system due to HIV infection. The medicine contains the active substance ganciclovir. It belongs to a group of medicines called ‘antivirals’.

Normally your immune system can stop CMV infection. However, in people with a poor immune system because of HIV that is not being controlled by proper treatment, CMV infection can be severe and cause serious effects.

CMV can infect any part of the body, including the retina of the eye (‘CMV retinitis’), which can affect eyesight. In most people with CMV retinitis, [HA515 trade name] slows down or prevents the spread of CMV to healthy cells, thereby protecting eyesight from damage.

#### **2. What you need to know before you are given [HA515 trade name]**

##### **Do not take [HA515 trade name] if:**

- You are allergic to ganciclovir, valganciclovir or any of the ingredients of this medicine (listed in Section 6).
- You are breastfeeding (see section on Pregnancy and breastfeeding below).

You must not be given [HA515 trade name] if any of the above apply to you. If you are not sure, talk to your healthcare provider before you are treated with [HA515 trade name].

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†Trade names are not prequalified by WHO. This is the national medicines regulatory agency’s responsibility.

## Warnings and precautions

Talk to your healthcare provider before you have [HA515 trade name] if you:

- You are allergic to aciclovir, valaciclovir, penciclovir, or famciclovir (medicines used for viral infections)
- have low numbers of white blood cells, red blood cells or platelets in your blood
- have had blood problems in the past that have been caused by medicines
- are having radiotherapy or have had it recently.
- have kidney problems.
- you or your partner might become pregnant during treatment. See the section on ‘Pregnancy and breastfeeding’.

If any of the above apply to you, or if you are not sure, talk to your healthcare provider before you have [HA515 trade name].

## Other medicines and [HA515 trade name]

Tell your healthcare provider if you are taking any other medicine or if you have recently taken other medicines. This is because [HA515 trade name] can affect the way some medicines work. Also some other medicines can affect the way [HA515 trade name] works or increase the risk of side effects.

In particular, tell your health care provider if you are taking:

- 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 – used after an organ transplant,
- vincristine, vinblastine, doxorubicin – used for cancer,
- hydroxyurea – used for a problem called polycythemia, sickle cell disease and cancer,
- didanosine, zidovudine, tenofovir or any other medicines used for HIV,
- cidofovir and foscarnet-used to treat cytomegalovirus retinitis.

## Children and adolescents

There is limited information on how safe or effective ganciclovir is as a treatment for CMV disease in children under 12 years.

## Pregnancy, breastfeeding and fertility

### *Pregnancy*

[HA515 trade name] may harm an unborn baby. It 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.

### *Contraception*

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

- If you are a **woman** who could get pregnant – use contraception while you are using [HA515 trade name]. Also do this for at least 30 days after [HA515 trade name] has been stopped.

- If you are a **man** whose female partner could get pregnant – use a barrier method of contraception (such as condoms) while you are using [HA515 trade name]. Also do this for at least 90 days after [HA515 trade name] has been stopped.

If you or your partner becomes pregnant while one of you is using [HA515 trade name], talk to your doctor straight away.

#### *Breastfeeding*

Do not use [HA515 trade name] if you are breastfeeding. If your doctor wants you to start using [HA515 trade name], you must stop breastfeeding before you start using the medicine. This is because [HA515 trade name] may pass into breast milk and affect your child.

#### *Fertility*

[HA515 trade name], may affect fertility. [HA515 trade name], 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 Cymevene.

#### **Driving and using machines**

You may feel sleepy, dizzy, confused or shaky, or you may lose your balance or have fits while using [HA515 trade name]. If this happens, do not drive or use any tools or machines.

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

### **3. How [HA515 trade name] is given**

Always use [HA515 trade name] exactly as prescribed by your health care provider.

You should check with your health care provider if you are not sure. [HA515 trade name] will be given to you by a doctor or health care provider through a small tube as a drip 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 [HA515 trade name] 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 health care provider will work out how much to give you.
- How often you have [HA515 trade name] 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, or you may be switched to a different medicine that can be taken by mouth.
- Your 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 the infection affects your eyes (CMV retinitis) you will have regular eye checks as well.

#### **If you are given more [HA515 trade name] than you should have**

- Your medicine will be given to you by your health care provider, who will work out the right dose for you, so it is unlikely you will be given too much of the medicine.
- If you are given too much [HA515 trade name] 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 [HA515 trade name], tell your health care provider.

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

#### **If you stop using [HA515 trade name]:**

Do not stop using [HA515 trade name] without talking to your health care provider. Stopping before your health care provider has confirmed the infection is under control may allow your symptoms to come back.

#### 4. Possible side effects

Like all medicines, [HA515 trade name] can cause side effects, although not everybody gets them. If you get any side effects, particularly if severe and persistent, or have any change to your health that you think may be due to [HA515 trade name], you should speak to your healthcare provider.

##### ***Very common side effects (affects more than 1 in 10 users):***

- 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
- thrush and oral thrush
- upper respiratory tract infections (eg. Sinusitis, tonsillitis)
- loss of appetite
- headache
- cough
- feeling short of breath
- diarrhoea
- feeling or being sick
- abdominal pain
- eczema
- feeling tired
- fever

##### ***Common side effects (affect between 1 and 10 users in 100):***

- Infections of the blood. The signs include high temperature (fever), chills, palpitations, confusion and slurred speech.
- Reduced number of platelets in your blood. The signs include bruising easily and nose bleeds, blood in urine or stools or bleeding from gums, the bleeding could be severe.
- Reduction in all the types of cells in your blood. The signs include feeling tired, bruising easily, being short of breath and nose bleeds.
- Pancreatitis. The signs of pancreatitis include severe pain in the stomach which spreads to your back
- fits ('convulsions')
- 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 (affect fewer than 1 in 100 people)***

- failure of the bone marrow to produce blood cells
- hallucinations the signs of hearing or seeing things that not real
- abnormal thoughts or feelings, losing contact with reality
- failure of kidney function
- feeling agitated
- tremor, shaking
- deafness
- uneven heart beat
- hives, dry skin
- blood in urine
- infertility in men-[HA515 trade name] may stop sperm production. This can be temporary or permanent.
- chest pain

***Rare (affect up to 1 in 1000 people)***

Severe allergic reaction. 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.

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

**Reporting of side effects**

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

**5. How to store [HA515 trade name]**

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

[HA515 trade name] must not be stored above 30°C. It should be protected from light.

This medicine must not be used after the expiry date stated on the label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider 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 [HA515 trade name] contains**

- The active ingredient is ganciclovir (as sodium). 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 [HA515 trade name].

**What [HA515 trade name] looks like and contents of the pack**

[HA515 trade name] is a powder, supplied in a glass vial. Before it is given, [HA515 trade name] 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 [HA515 trade name] are supplied in packs of 10.

### Supplier and Manufacturer

#### *Supplier*

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For any information about this medicine, contact the local representative of the supplier.

**This leaflet was last revised in May 2024.**

*Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>*