

Cymevene®

contains the active ingredient ganciclovir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CYMEVENE.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given CYMEVENE injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

What CYMEVENE is used for

CYMEVENE contains the active ingredient ganciclovir.

CYMEVENE belongs to a class of medicines used to treat viral infections. It works by stopping certain viruses from growing in the body.

CYMEVENE acts against a certain type of herpes virus called cytomegalovirus or CMV. CMV causes infections mainly in people with poor immunity. Poor immunity can be caused by HIV/AIDS or some transplant medications.

CYMEVENE helps control CMV eye infections in AIDS patients and in other patients who have poor immunity, which if left untreated can cause blindness. CYMEVENE

is not a cure for CMV eye infections and is not effective against any underlying HIV-infection.

CYMEVENE may also be used to treat CMV lung infections in bone marrow transplant patients.

CYMEVENE may also be used to prevent CMV infection and disease in patients following bone marrow or solid organ transplantation.

Ask your doctor if you have any questions about why CYMEVENE has been prescribed for you.

Your doctor, however, may have prescribed CYMEVENE for another purpose.

CYMEVENE is not addictive.

This medicine is available only with a doctor's prescription.

Before you are given CYMEVENE

Animal and other laboratory studies have shown CYMEVENE has caused infertility, birth defects and cancer. It is possible that these effects may also occur in humans.

When you must not be given it

Do not use CYMEVENE if

- 1. you have had an allergic reaction to CYMEVENE or Vitrasert® implant, or other drugs from the same family: valganciclovir (Valcyte®); aciclovir (e.g. Zovirax®, Acyclo-V®, Acihexal®, Lovir® or Zyclir®);**

valaciclovir (e.g. Valtrex®, Zelitrex®, Xerebid®, Valnir®)

Some of the symptoms of an allergic reaction may include:

- shortness of breath
 - wheezing or difficulty breathing
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching or hives on the skin.
- 2. you have very low blood counts for platelets (which help clotting) or neutrophils (a type of white blood cell which defends against infection) or haemoglobin (a substance that carries oxygen in the blood)**
 - 3. you are pregnant**
your baby may absorb this medicine in the womb and therefore there is a high likelihood of harm to the baby
 - 4. you are breast-feeding or intend to breast-feed**
CYMEVENE may pass into breast milk and therefore there is a possibility that the breast-fed baby may be affected
 - 5. the package is torn or shows signs of tampering**
 - 6. the expiry date (EXP) printed on the pack has passed.**
If you take this medicine after the expiry date has passed, it may not work as well.
- If you are not sure if you should be receiving CYMEVENE, talk to your doctor.**

Use in Children

There is very little information available on the use of CYMEVENE in children less than 12 years and safety and

effectiveness in children has not been proven. Children that take CYMEVENE, when grown-up, have an increased risk of cancer and, also, adverse effects when trying to have children of their own. Therefore CYMEVENE should only be used if these risks are outweighed by the benefits of treatment.

Before you are given it

Tell your doctor if

1. you are allergic to any other medicines, foods, dyes or preservatives.

Especially any medicine which you have taken previously to treat your current condition (e.g. valganciclovir, valaciclovir)

2. you have any other health problems, especially the following:

- you have a history of low blood counts for platelets (thrombocytopenia), neutrophils (neutropenia) or red blood cells/haemoglobin (anaemia)
- you have or previously have had poor kidney function

3. you are pregnant or plan to become pregnant

4. you are breast feeding or plan to breast feed

5. you are a woman who could become pregnant and you are not using contraception

- you must use a reliable form of contraception during CYMEVENE therapy, and for at least 30 days after stopping CYMEVENE, unless you are not sexually active.

6. you are a sexually active man

- you should use condoms during and for at least 90 days following treatment with CYMEVENE unless it is certain that your female partner is not at risk of pregnancy.

If you have not told your doctor about any of the above, tell them

before you start taking CYMEVENE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with CYMEVENE. These medicines include:

- probenecid (e.g. Benemid®)
- zidovudine (AZT, Retrovir®, Combivir®)
- didanosine (ddI or Videx®)
- imipenem/cilastatin (Primaxin®)
- medicines for the treatment of cancer
- other medicines for the treatment of HIV or HIV-related infections
- mycophenolate mofetil (CellCept®), a medicine used to prevent rejection of transplanted organs
- other medicines used to prevent rejection of transplanted organs

These medicines may be affected by CYMEVENE, or may affect how well it works. You may need to receive different amounts of your medicine, or you may need to receive different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while receiving CYMEVENE.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How CYMEVENE is given

CYMEVENE is added to an infusion bag and given as a 'drip' into a vein, usually over a period of one hour.

CYMEVENE is usually given once or twice a day.

Your doctor will decide what dose of CYMEVENE you will receive. This depends on how serious your infection is as well as your kidney function.

While you are receiving CYMEVENE

Things you must do

Tell all doctors, dentists, and pharmacists who are treating you that you are being given CYMEVENE.

See your doctor regularly so that your CMV disease, blood cell counts and any other potential side effects may be monitored carefully.

If blood cell counts are low then this may reduce your ability to fight infection, or for your blood to clot efficiently. If left undetected these effects on blood cells may contribute to death or serious illness.

If you have a CMV eye infection, you must also see your doctor regularly to monitor the condition of your retina (part of the eye).

Tell your doctor if you become pregnant while receiving CYMEVENE.

If there is a possibility of your partner becoming pregnant, a barrier contraceptive should be used while receiving CYMEVENE and for 90 days after stopping.

Things you must not do

Do not take any other medicines whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how CYMEVENE affects you.

CYMEVENE may cause drowsiness, dizziness, confusion or seizures (fits) in some people and therefore may affect alertness. Make sure you know how you react to CYMEVENE before you drive a car or operate machinery or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well after you have been given CYMEVENE.

CYMEVENE helps most people with CMV infections but it may have unwanted side effects in some people.

Unwanted effects may be due to CYMEVENE, other medications, or any disease or condition you may also have. You should notify your doctor if these or any other effects occur.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment or a change of therapy if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Many unwanted effects commonly reported in people with HIV appear to be related to their medical condition. The following list are unwanted effects seen in people receiving intravenous CYMEVENE which may or may not be caused by their medication:

- low white blood cell counts

- anaemia (low red blood cell counts)
- diarrhoea
- nausea and/or vomiting
- feeling of weakness
- weight loss
- low blood platelet count
- other infections
- injection site soreness or redness.

Tell your doctor if you notice any of the following and they are worrying you:

- pain
- loss of feeling or tingling
- itching
- skin rash
- difficulty in swallowing
- cough
- nervousness or feeling anxious
- confusion
- headache
- fluid buildup
- indigestion
- shortness of breath.

If you notice any of the following you should see your doctor immediately:

- a deterioration or worsening of your eye sight even if you are receiving CYMEVENE
- bruising or purple spots
- any sign of infection such as fever, chills, sore throat or mouth ulcers
- rapid or irregular heartbeat or sudden fevers
- tiredness
- severe allergic reactions causing swelling, rash or itching
- severe blisters and bleeding in the lips eyes, mouth, nose and genitals
- pain or inflammation in your chest, stomach or intestines
- bleeding (haemorrhage)
- collapse, numbness or weakness of the arms or legs, headache, dizziness and confusion, visual disturbance, difficulty

- swallowing, slurred speech and loss of speech
- pain, swelling or joint stiffness
- seizures (fits)
- change in the amount of urine you pass.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

After receiving CYMEVENE

Storage

CYMEVENE vials and infusion bags will be stored in the pharmacy or on the ward.

Product Description

What CYMEVENE looks like

CYMEVENE is available as a freeze-dried powder in clear glass vials. It will be made up into an infusion bag before being given to you.

Ingredients

Active ingredient

Each 10 mL CYMEVENE vial contains:

- 543 mg of ganciclovir sodium equivalent to 500 mg of ganciclovir

There are no other ingredients in CYMEVENE vials.

CYMEVENE does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Distributor

CYMEVENE is distributed by:

Pharmaco (Australia) Ltd
Suite 1A, Level 2
802 Pacific Highway
Gordon NSW 2072
AUSTRALIA

Under license of CHEPLAPHARM
Arzneimittel GmbH, Germany

Please check with your pharmacist
for the latest Consumer Medicine
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