

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CYMEVENE® Freeze dried powder

Ganciclovir 500 mg

Read all of this leaflet carefully before you receive CYMEVENE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CYMEVENE has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

1. WHAT CYMEVENE CONTAINS

Each vial contains the equivalent of 500 mg of the active ingredient called ganciclovir. The powder is made up by dissolving it in a liquid for injection.

The other ingredients are: Sodium hydroxide, hydrochloric acid and water for injection.

2. WHAT CYMEVENE IS USED FOR

Ganciclovir is an anti-viral medicine which acts by stopping the CMV virus reproducing and invading/infecting one or more organs of the body where it causes inflammation of the invaded body organ.

CYMEVENE for intravenous infusion is used for the prevention or treatment of cytomegalovirus (CMV) infections in patients 12 years of age or older, whose immune system is not functioning fully because of the effect of other infections (e.g. AIDS) or drugs medicines used in patients who had an organ transplant or are on treatment for cancer.

3. BEFORE YOU ARE ADMINISTERED CYMEVENE

You should not use CYMEVENE:

- If you are allergic to the active ingredient in CYMEVENE (ganciclovir) or to any of its inactive ingredients or to valganciclovir or acyclovir.
- If you are pregnant or breastfeeding your baby.
- For the treatment of CMV infections in your unborn baby or in newborn babies.
- If you are using medicines aimed at slowing down or suppressing the rate of your blood cell production.

Take special care with CYMEVENE:

Talk to your doctor or healthcare professional before using CYMEVENE:

- If you are allergic to aciclovir, valaciclovir, penciclovir or famciclovir. These are medicines used for viral infections.
- If 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.
- If you had problems with your blood cell counts caused by medicines you have used in the past.
- If you have kidney problems. Your doctor will request laboratory tests to assess your kidney function and blood cells. You may need a lower dose and your blood cell counts will frequently be checked during treatment.
- If you are receiving radiotherapy.

Receiving CYMEVENE with food and drink:

CYMEVENE contains 43 mg of sodium (salt) in each 500 mg dose. This should be taken into consideration if you are on a controlled sodium (salt) diet.

Pregnancy and Breastfeeding:

You must not use CYMEVENE if you are pregnant or breastfeeding your baby. CYMEVENE may cause serious harm to your unborn baby or your baby if you are breastfeeding your baby.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before being administered CYMEVENE.

Fertility:

Your fertility may be temporary or permanently impaired. You should consider sperm or ovum conservation before starting treatment with CYMEVENE.

If you are a woman of childbearing age, you should use contraception if you are treated with CYMEVENE. You should continue using contraception for 30 days after your treatment with CYMEVENE has been stopped.

If you are a male on treatment with CYMEVENE you should use a condom whilst on treatment and continue to use a condom for 90 days after your treatment with CYMEVENE has been stopped.

Driving and using machinery:

CYMEVENE may interfere with driving and using machines. You should not drive and use machines until you know how treatment with CYMEVENE affects you.

You may feel tired, dizzy, confused, have impaired vision or shaky, or you may lose your balance or have fits while using CYMEVENE.

Taking other medicines with CYMEVENE

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

- If you have low numbers of certain types of blood cells (known as white blood cells and platelets).
This will be detected in a blood test performed by your doctor.
- If you are already on zidovudine (ZDV, AZT). Taking this together with CYMEVENE may lead to a severe reduction in the number of white blood cells or red blood cells in your blood.

- If you have any kidney problems.
- It is very important that both men and women of child bearing/procreation potential use effective contraception during treatment with CYMEVENE; men should continue to use condoms for 90 days following treatment (see POSSIBLE SIDE-EFFECTS)
- Use in a child must be carefully considered by the doctor.
- Make sure your doctor knows if you are taking the following medicines: probenecid, imipenem-cilastatin, didanosine, mycophenolate, dapsone, pentamidine, flucytosine, vincristine, vinblastine, adriamycin, amphotericin B, trimethoprim/sulfa combinations, other anticancer/antiviral drugs.

4. HOW TO RECEIVE CYMEVENE

Do not share medicines prescribed for you with any other person.

CYMEVENE should always be administered by a healthcare professional.

Receiving CYMEVENE:

- CYMEVENE should always be used as directed by your doctor. The doctor will ensure that it is correctly made into a solution before use.
- The solution is usually administered by your doctor or nurse into a vein via an infusion/drip set. This usually takes at least one hour.
- The initial dose is usually 5 milligrams (mg) for every kilogram (kg) that you weigh. The dose may be administered every 12 hours for 7 – 21 days.
- After this, the same dose may be given once a day, every day, for 7 days a week. Otherwise, 6 mg for every kg that you weigh (6 mg/kg) may be given once a day for 5 days each week.
- If your kidney function is less than normal, your doctor may prescribe a different dose.
- To assess your treatment, you may need to have regular blood tests.

Your doctor will tell you how long your treatment with CYMEVENE will last. Do not stop treatment early if you are sick after being administered CYMEVENE.

If you have the impression that the effect of CYMEVENE is too strong or too weak, tell your doctor or pharmacist.

If too much CYMEVENE is given:

Since a healthcare professional will administer CYMEVENE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If a dose of CYMEVENE is missed:

It is important that you continue to use your medicine according to the instructions of your doctor and that you do not miss any doses. However, if you do miss a dose contact your doctor or the hospital without any delay.

Effects when treatment with CYMEVENE is stopped:

Do not stop using CYMEVENE treatment without talking to your doctor first. If you have any further questions on the use of CYMEVENE talk to your doctor, pharmacist or nurse.

5. POSSIBLE SIDE-EFFECTS

CYMEVENE can have side effects.

Not all side-effects reported for CYMEVENE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving CYMEVENE, please consult your doctor, pharmacist or other health care professional for advice.

There is a concern regarding the possibility of developing cancers or permanent harm to your reproductive organs (impairment of fertility) with long term use especially when treatment is initiated at a young age.

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects – your doctor may have to stop your treatment with CYMEVENE tell you to stop taking CYMEVENE and you may need urgent medical treatment:

Frequent:

- 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.
- 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.

Less-Frequent:

- 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:

Frequent:

- diarrhoea
- feeling short of breath.
- headache
- trouble sleeping
- fever, chills or night sweats
- feeling tired, dizzy, weak or generally unwell
- feeling depressed, anxious, confused or having abnormal thoughts
- pain
- ear pain
- hands or feet feeling weak or numb, which may affect your balance
- muscle pain or spasms
- back, chest or joint pain
- sight problems or eye pain
- eczema, skin problems, itching
- changes to your sense of touch, tingling, tickling, pricking or burning feeling

- fits
- cough
- feeling or being sick
- problems swallowing
- changes to the way things taste
- loss of appetite, anorexia or weight loss
- stomach pain, constipation, wind, indigestion
- urine infection – signs include fever, passing urine more often, pain when passing urine
- thrush and oral thrush
- bacterial skin infection – signs include red, painful or swollen skin
- blood poisoning (sepsis)
- changes in blood cell counts
- liver and kidney problems shown in tests
- a skin reaction where the medicine was injected – such as inflammation, pain and swelling.

Less-Frequent:

- hair loss
- deafness
- mouth ulcers
- hives, dry skin
- feeling agitated or nervous
- eye infection (conjunctivitis)
- abnormal thoughts or feelings, losing contact with reality
- blood in urine
- tremor, shaking
- swollen stomach
- uneven heartbeat
- low blood pressure, which may make you feel dizzy or faint

- serious kidney problems shown in tests
- low red blood cell counts shown in tests
- infertility in men
- pancreatitis – signs are severe stomach pain which spreads into your back.
- rash
- hallucinations – hearing or seeing things that are not real.

Side effects in children and adolescents

The following side effects are more likely in children:

- fever
- stomach pain
- low white blood cell counts.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. STORING AND DISPOSING OF CYMEVENE

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package.

Keep the container in the outer carton.

There are no special storage instructions for this medicine.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF CYMEVENE

The vials are available in packs of 5.

8. IDENTIFICATION OF CYMEVENE

CYMEVENE freeze dried powder is a white to off-white powder in a vial.

9. REGISTRATION NUMBER

Y/20.2.8/291

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,

South Tower, 1st Floor,

Sandton 2196,

South Africa.

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11. DATE OF PUBLICATION

Registration: 18 June 1992

Last revision: 09 March 2023