

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CYMEVENE[®] Freeze dried powder

Ganciclovir 500 mg

Read all of this leaflet carefully before you start taking/using 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.

2. WHAT CYMEVENE IS USED FOR

Cytomegalovirus (CMV) is a virus that can infect any part of the body, including the retina of the eye, where it causes inflammation (CMV retinitis), and problems with eyesight.

Ganciclovir is an antiviral drug and it acts by stopping the CMV virus reproducing and invading healthy cells. This may slow down the progression of your retinitis.

Cymevene for intravenous infusion is used for the prevention or treatment of cytomegalovirus (CMV) infections in patients whose immune system is not functioning fully because of the effect of other infections or drugs.

3. BEFORE USING/TAKING CYMEVENE

- If you are allergic to the active ingredient in Cymevene or to any of its inactive ingredients or to acyclovir.
- If you are pregnant or breastfeeding.

Take other medicines with CYMEVENE

Please tell your doctor, nurse or midwife if your baby is taking or has recently taken any other medicines. This includes medicines that you buy without a prescription, complementary or traditional medicines. This is because CYMEVENE can affect the way some medicines work. Also some other medicines may affect the way CYMEVENE works.

- 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.
- If you feel dizzy, tired, shaky or confused while taking this medicine, do not drive or operate machinery.
- 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 CYMEVENE IS GIVEN

CYMEVENE Powder for Infusion

- This product 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 a plastic tube. 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.
- In the unlikely event of overdose, contact your doctor, pharmacist or nearest hospital straight away.

If you get more CYMEVENE than they should

If you get more CYMEVENE than they should, you must talk to a doctor, nurse, midwife or pharmacist.

You must not take more than the recommended dose. If you take more doses than advised, this could cause severe reduction in white blood cells, for which you may need to be hospitalised. Contact your doctor or the hospital immediately if you have taken an overdose.

If you forget to take your CYMEVENE

It is important that you continue to take your medicine according to the instructions on the label and that you do not miss any doses. However, if you do miss a dose, take it as soon as you remember and take the next dose at the usual time.

Do not share CYMEVENE prescribed for your baby with another person.

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5. POSSIBLE 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 taking CYMEVENE, consult your midwife, doctor, pharmacist or other health care professional for advice.

Although this medicine can fight CMV retinitis, it may have some serious side-effects. Your doctor may advise stopping your treatment either temporarily or permanently, depending on your condition. You should discuss all the possible side-effects of CYMEVENE with your doctor.

CYMEVENE may cause the white cells in the bloodstream to decrease in number, a condition called neutropenia. This makes the body more prone to infections and less able to deal with them satisfactorily. This is particularly important if you have previously had a disturbance of bone marrow function, such as after exposure to radiation or drugs known to damage bone marrow, or as a reaction to other medications. You

should discuss with your doctor the signs to look out for which may indicate that this is happening to you. The common early signs include infections of the gums, throat and upper airways.

The drug may also suppress the production of platelets. These are cells which are found in the bloodstream and which are important for blood clotting. A lack of platelets will put you at an increased risk of bruising and bleeding episodes. If these occur, you should see your doctor immediately.

Some people experience anaemia, i.e. reduction in the number of red blood cells, which may cause a feeling of lack of energy and breathlessness on exertion.

Tumours have been found in laboratory animals receiving this drug, although at this time there is no similar information from human studies. The drug also has damaging effects on the reproductive system. When used in men, it may decrease the number of sperm in the semen, and this may be complete and irreversible. In women, not only may there be suppression of fertility, but pregnancy during treatment is likely to lead to the birth of a malformed child.

If you feel dizzy, tired, shaky or confused while taking this medicine, do not drive or operate machinery.

Additionally, the following side-effects have also been reported:

Whole body: chills, fever, rash, spots, cold sores, acne, itchy skin, infection, feeling unwell (malaise), swelling, abnormal liver function tests or abnormal blood tests, itching, skin inflammation, hair loss, muscle pain or weakness, pain, sensitivity to light, sweating.

Heart and blood system: high or low blood pressure, abnormal heart beat, blood clots, skin flushing, migraine, decrease in the amount of sugar or potassium in your blood.

Nervous system: abnormal thoughts or dreams (nightmares), coma (unconsciousness), confusion, dizziness, headache, nervousness, tingling of fingers/toes, numbness, depression, changes of mood, sleepiness or insomnia, tremor, abnormal walk, dry mouth, fits.

Digestive system: feeling or being sick, anorexia (loss of appetite), diarrhoea, indigestion, bleeding, abdominal pain, pancreatitis, constipation, heartburn, difficulty swallowing, flatulence (wind), belching, incontinence, mouth ulcers.

Injection site: pain, inflammation, infection.

Other: eye pain, abnormal eye-sight, retinal detachment, blindness, eye inflammation, breast pain, enlarged abdomen, difficulty breathing, blood in urine, an increase in some metabolic enzymes, cough, deafness, unusual taste, kidney problems, frequent urination, infection in the kidneys or bladder.

6. STORING AND DISPOSING OF CYMEVENE

Use by date

Do not use your medicine after the expiry date, which is printed on the pack.

Storing your medicine

- Keep your medicine in a safe place where children cannot reach it.
- It is best to store your medicine below 30 °C.

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,

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11. DATE OF PUBLICATION

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