

EMPOVIR®

Cidofovir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about EMPOVIR®. 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 taking EMPOVIR against the benefits that are expected. This leaflet does not contain everything about EMPOVIR. Your doctor has been provided with full information and can answer any questions you may have. Follow your doctor's advice even if it differs from what is in this leaflet.

Please read this leaflet carefully and keep it in a safe place so you may refer to it later.

What EMPOVIR is used for

Cidofovir is used to treat an eye infection called CMV retinitis in patients with AIDS (Acquired Immunodeficiency Syndrome). Cidofovir will not cure CMV retinitis but may improve your condition by delaying progression of the disease. The safety and efficacy of cidofovir has not been demonstrated in diseases other than CMV retinitis in patients with AIDS.

Cidofovir must be administered by a healthcare professional (doctor or nurse) in a hospital setting.

What is CMV retinitis?

CMV retinitis is an eye infection caused by a virus named

cytomegalovirus (CMV). CMV attacks the retina of the eye and may cause loss of vision, and eventually lead to blindness.

Patients with AIDS are at high risk of developing CMV retinitis or other forms of CMV disease such as colitis (an inflammatory bowel disease). Treatment for CMV retinitis is necessary to reduce the potential for blindness.

How EMPOVIR works

Cidofovir is an antiviral medicine which blocks the replication of CMV by interfering with viral DNA production.

The use of Cidofovir to treat your condition can lead to side-effects, which are discussed below.

Before you are given EMPOVIR

When you must not be given it

You must not have EMPOVIR if you have a history of severe allergic reactions to EMPOVIR or to any of the ingredients listed at the end of this leaflet.

Do not have EMPOVIR if you have, or have had, any of the following medical conditions, unless you have discussed it with your doctor:

- If you are allergic to cidofovir or any of the other ingredients of this medicine (listed in section Product description).

- If you have ever had kidney disease.
- If you cannot take the medicine probenecid because of a serious allergy to probenecid or other sulfacontaining medicines (e.g. sulfamethoxazole).
Talk to your doctor or pharmacist or nurse before using cidofovir.
- Kidney damage is the major side effect of cidofovir treatment. Therefore, your doctor may need to monitor carefully, particularly if you already have kidney problems or are on haemodialysis.
- If you have diabetes mellitus cidofovir should be used with caution in diabetic patients due to the potential increased risk of developing low pressure in the eye (ocular hypotony).

During treatment with cidofovir you should receive regular follow-up eye examinations for possible eye irritation, inflammation or swelling. If you get pain, redness or itching of the eye or changes in your vision, tell your doctor promptly.

Cidofovir caused reduced testes weight and low sperm count (hypospermia) in animals. Although not observed in human studies of cidofovir, such changes may occur in humans and cause infertility. Men should practice barrier birth control methods during and for 3 months after treatment with cidofovir. Cidofovir is not used for the treatment of HIV infection.

Cidofovir will not stop you passing HIV infection onto other people so you should continue to take

precautions to avoid infecting others.

Children

Cidofovir has not been studied in children. Therefore, this medicine should not be used in children.

Females: You should not be given cidofovir if you are pregnant. If you become pregnant while receiving this medication, you must inform your doctor immediately. Cidofovir has been shown to cause damage in unborn animals and should not be used during pregnancy unless the potential benefits justify the risks to the foetus. If you could get pregnant, you must use an effective method of contraception to stop you getting pregnant during treatment with cidofovir and for 1 month afterwards.

You should not be given cidofovir if you are breastfeeding.

It is not known whether cidofovir is passed on to the baby in human milk. Because many medicines are passed through to human milk, nursing mothers should stop cidofovir or stop breast-feeding if they continue to receive cidofovir.

In general, women with HIV should not breast-feed in order to avoid passing HIV to their infant through the milk.

If you are not sure whether you should start having EMPOVIR, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to:

- any other medicines

Tell your doctor if you have or have had any medical conditions, especially the following:

- diabetes mellitus
- kidney problems

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,

including medicines obtained without a prescription, as these may interact with cidofovir or probenecid. It is very important to tell your doctor if you are receiving other medicines that may damage your kidneys.

These include:

- tenofovir containing medicines, used to treat HIV-1 infection and/or chronic infection and/or chronic hepatitis B infection
- aminoglycosides, pentamidine or vancomycin for bacterial infections)
- amphotericin B (for fungal infection)
- foscarnet (for viral infection)
- adefovir (for HBV infection)

These medicines must be stopped at least 7 days before taking cidofovir. Probenecid may interact with other medicines commonly used in the treatment of AIDS and AIDS-related illnesses, such as zidovudine (AZT). If you are taking zidovudine, you should discuss with your doctor whether to temporarily stop taking zidovudine or decrease the dose of zidovudine by 50% on days when cidofovir and probenecid are given. The potential for interactions between cidofovir and anti-HIV protease inhibitors has not been studied.

Cidofovir with food and drink

Food should be taken before you are given cidofovir. Your doctor may instruct you to drink plenty of fluids before receiving cidofovir.

If you have not told your doctor about any of the above, tell them before you start having EMPOVIR.

While you are receiving EMPOVIR

Things you must do:

- Tell your doctor immediately if you become pregnant while taking EMPOVIR.
- Tell all of the doctors, dentists and pharmacists who are treating you that you are taking EMPOVIR.
- If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking EMPOVIR.
- Be sure to keep all your doctor's appointments so your progress can be checked. Your doctor may want to do some tests from time to time to check on your progress and detect any unwanted side effects.

Things to be careful of:

- Cidofovir may cause short-term side effects such as fatigue or weakness. If you drive or operate machinery, discuss this with your doctor to get advice about stopping these activities based upon your disease and your tolerance of the medicine.
- EMPOVIR contains 2.5 mmol (or 57 mg) sodium per vial which should be taken into consideration if you are on a controlled sodium diet.

How EMPOVIR is given

EMPOVIR is given by intravenous infusion (a drip into a vein). It must not be administered by other methods including intraocular injection (direct injection into the eye) or topically (on the skin).

EMPOVIR must be given by a doctor or nurse with appropriate experience in treating people with AIDS.

The doctor or nurse will transfer the appropriate dose of EMPOVIR from the vial to an infusion bag containing 100 mL 0.9% (normal) saline solution. The entire volume of the bag will be infused into your vein at a constant rate over a period of 1 hour using a standard infusion pump. The recommended dose, frequency of use, or rate of infusion must not be exceeded. At the end of this leaflet, there is further information for healthcare professionals on how to administer EMPOVIR To lower the risk of kidney damage, probenecid tablets and intravenous fluids (saline solution) must be given on the day of each EMPOVIR(See sub-sections “How to take probenecid with EMPOVIR” and “How IV fluids are given before EMPOVIR” below.)

Dose in adults

The dose you will need is calculated based on your body weight.

Starting (induction) treatment

The recommended dose of EMPOVIR in patients with normal kidney function is 5 mg per kg of body weight given once weekly for two consecutive weeks.

Maintenance treatment

Beginning two weeks after completion of induction treatment, the recommended maintenance dose of EMPOVIR in patients with normal kidney function is 5 mg per kg of body weight given once every two weeks.

Dose adjustment

If you have kidney problems, EMPOVIR may not be appropriate treatment for you. Samples of your urine and/or blood will be taken before each infusion of EMPOVIR and used for testing kidney function.

For patients with evidence of decreased kidney function, your EMPOVIR dose may be interrupted or stopped depending on your individual case.

If you use more EMPOVIR than you should

If you have accidentally been given more EMPOVIR than prescribed for you, tell your doctor immediately.

How to take probenecid with EMPOVIR

Probenecid tablets are given to lower the risk of kidney damage. You must take 3 doses of probenecid tablets orally on the same day as EMPOVIR as shown in the following table:

Time	Dose
3 hours before start of cidofovir	2 g probenecid
2 hours after end of cidofovir	1 g probenecid
8 hours after end of cidofovir	1 g probenecid
Total	4 g probenecid

Probenecid is only taken on the same day that EMPOVIR is given.

How IV fluids are given before EMPOVIR

Normal saline is given to lower the risk of kidney damage. You should receive a total of one litre of 0.9% (normal) saline solution intravenously (as a drip into a vein) before each EMPOVIR dose. The saline solution should be infused over a 1 hour period immediately before the EMPOVIR. If you can tolerate the additional fluid load, your doctor may administer a second litre of fluid. If administered, the second litre of saline should be given either at the start of the EMPOVIR or immediately afterwards, and infused over a 1 to 3 hour period.

Your doctor may also tell you to drink plenty of fluids.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

How long is EMPOVIR given

EMPOVIR is usually given every two weeks after induction treatment. Your doctor will decide how many such maintenance doses you will need.

Ask your doctor if you want to know more about the dose of EMPOVIR you receive.

Overdose

As EMPOVIR is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects after being given EMPOVIR, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital. You may need urgent medical attention.

Symptoms of a Cidofovir overdose include the side effects listed below in the "Side Effects" section, but are usually of a more severe nature.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving EMPOVIR.

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

Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately. Do not be alarmed by the following lists of side effects. You may not experience any of them.

Very commonly observed side effects with cidofovir are: protein in urine, increased blood creatinine (a measure of kidney function), low white blood cell counts, hair loss, fever, abnormal physical weakness or lack of energy, headache, feeling sick (nausea), being sick (vomiting), skin rash.

Other commonly side effects include chills, reduced pressure in

the eyes, inflammation of the eyes, any pain, redness or itching of the eyes, kidney failure, difficulty breathing (dyspnoea), loose stools (diarrhoea). These should be immediately reported to your doctor.

Tell your doctor as soon as possible if you notice any of the following side effect since these may be serious: allergic reaction, infection, chills, no relief from eye infection, loss of appetite, diarrhoea, liver problems, decrease in red blood cell counts, liver toxicity, shortness of breath, inflammation of the eyes, kidney failure, abnormally low level of phosphate in blood, rare disorder of kidney function that results in excess amounts of glucose, salts, uric acid, potassium, and certain amino acids being excreted in the urine, protein in urine, excess glucose in urine, feeling of incomplete urination, increased urea in blood (indicates decreased removal from blood by kidneys).

Very commonly observed side effects which may be due to probenecid are: feeling sick, being sick, rash and fever.

Commonly observed side effects which may be due to probenecid are: headache, chills, abnormal physical weakness or lack of energy.

The other side effects with probenecid include loss of appetite, gum pain, flushing, hair loss, dizziness, frequent urination, allergic reactions (itching, rash), rare serious disorder of skin and mucous membrane, decrease in number of all types of blood cells specifically red blood cell due to premature destruction, kidney and liver disease.

- You should also read the probenecid CMI.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Product Description

EMPOVIR is supplied as a sterile concentrate for dilution for intravenous infusion in clear, glass vials containing 375 mg of the active ingredient, cidofovir as the dihydrate formulated in 5 mL water for injections at a concentration of 75 mg/mL. The formulation is pH-adjusted with sodium hydroxide (and hydrochloric acid if needed) and contains no preservatives.

Active ingredient: Cidofovir as the dihydrate.

Other ingredient: sodium hydroxide, hydrochloric acid, water for injections

Storage

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

Do not use this medicine after the expiry date which is stated on the label.

Store below 25°C. Do not refrigerate or freeze.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Sponsored by

Emcure Pharmaceuticals Pty Ltd
Shop 3, 26 Henley Road,
Homebush, West
NSW, 2140, Australia

Registration Numbers

AUST R 287040

Where to get further information

Your doctor is the best person to answer any further questions you may have about EMPOVIR.

Anything your doctor tells you about EMPOVIR should be followed even if it is different from what is in this leaflet.

Date of Preparation: April 2018