VISTIDE®

cidofovir

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VISTIDE concentrated solution for injection. 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 treating you with VISTIDE against the benefits this medicine is expected to have for you.

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

Keep this leaflet with your medicine.
You may need to read it again.

What VISTIDE is used for

VISTIDE is used to treat cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). VISTIDE will not cure CMV retinitis but may improve your condition by delaying the progress of the disease.

What is CMV retinitis?

CMV retinitis is an eye infection caused by a virus named cytomegalovirus. CMV attacks the retina of the eye and may cause loss of vision, and eventually lead to blindness. Patients with AIDS have a high risk of developing CMV retinitis or other forms of CMV disease such as colitis (inflammation of the gut). Treatment of CMV retinitis is necessary to reduce the risk of blindness.

How VISTIDE works

VISTIDE is an antiviral medicine that works by blocking the replication of CMV and other human viruses such as herpes viruses.

Your doctor may have prescribed VISTIDE for another purpose.

Ask your doctor if you have any questions about why VISTIDE has been prescribed for you.
This medicine is available only with a doctor's prescription.

VISTIDE is not addictive.

Before treatment with VISTIDE

When VISTIDE must not be used

VISTIDE should not be used:

1. **if you have an allergy to:**
   - cidofovir
   - any of the other ingredients listed at the end of this leaflet (see Product description)
   - probenecid or other sulfur-containing medications
   Symptoms of an allergic reaction may include skin rash, itching, swelling of the face, lips or tongue or difficulty in breathing.
2. **if you have kidney damage**
3. **if you are using medications which may cause damage to the kidneys,** such as amphotericin B, foscarnet, intravenous pentamidine, intravenous aminoglycoside antibiotics (e.g. gentamycin, tobramycin), vancomycin and non-steroidal anti-inflammatory agents. You should stop using these medications at least 7 days before starting your treatment with VISTIDE.
4. **if you are pregnant or intend to become pregnant**
5. **if you are breast-feeding or plan to breast-feed**
6. **if the packaging is torn or shows signs of tampering**
7. **after the expiry date (EXP) printed on the carton label.**
   If VISTIDE is used after the expiry date, it may have no effect at all, or an entirely unexpected effect.

If you are not sure whether you should be treated with VISTIDE, talk to your doctor.

Before starting treatment with VISTIDE

You must tell your doctor about all of the following before you begin treatment with VISTIDE:

1. if you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.
2. if you have previously been treated with a medicine called foscarnet (used to treat viral infections caused by cytomegalovirus and herpes simplex).

If you have not told your doctor or pharmacist about any of the above, do so before you start taking VISTIDE injection.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

You should tell your doctor if you are receiving any other medicines that are known to damage the kidney, e.g. aminoglycosides, amphotericin B, foscarnet and intravenous pentamidine. As VISTIDE can cause kidney damage, it will be necessary to stop taking any other medicines that could also damage the kidneys at least 7 days before starting treatment with VISTIDE.

Probenecid interferes with the metabolism and excretion of many drugs. It is important to advise your doctor if you are taking any of the following:

- **paracetamol** and **aspirin**
- **aciclovir** (an antiviral medicine)
- ACE Inhibitors (used for high blood pressure and heart conditions)
- barbiturates and benzodiazepines (used to help patients sleep)
- **clofibrate** (a lipid-lowering agent)
- **methotrexate** (a medicine used for arthritis and to treat some types of cancer)
- **famotidine** (used for stomach ulcers)
- **frusemide** (a medicine for reducing blood pressure)
- non-steroidal anti-inflammatory drugs (used to reduce swelling)
- **theophylline** (a medicine used to treat asthma)
- **zidovudine (AZT):** If you are currently taking zidovudine, your doctor may temporarily discontinue this medicine or reduce your dose by 50% on the days when you receive VISTIDE therapy.

Ask your doctor or pharmacist if you're not sure if you are taking any of these medicines.

Using VISTIDE

VISTIDE is administered by intravenous infusion and must not be administered into the eye. VISTIDE must be administered by your doctor or health care professional.

To reduce the risk of kidney damage, probenecid tablets and intravenous saline solution must be administered with each VISTIDE infusion.

Follow all directions given to you by your doctor and pharmacist carefully.

You may be given a different dosage of VISTIDE depending on your condition and how you react to the medicine.

Women should use effective contraception while on VISTIDE and for one month after treatment with VISTIDE. Men should practice barrier contraceptive methods during and for 3 months after treatment with VISTIDE.

Dosing

Adults

Induction treatment: The recommended dose of VISTIDE in patients with normal kidney function is 5 mg/kg body weight (given as an intravenous infusion at a constant rate over one hour) administered once a week for two weeks.

Maintenance treatment: Beginning two weeks after completion of induction treatment, the recommended maintenance dose in patients with normal kidney function is 5 mg/kg (given as an intravenous infusion at a constant rate over one hour) administered once every two weeks.

Samples of urine and/or blood will be taken before each infusion of VISTIDE and used to test kidney function. For patients with decreased kidney function, your VISTIDE dose may be reduced or stopped, depending on your individual case.

Why is probenecid given with VISTIDE?

Probenecid tablets are given to reduce the risk of kidney damage. With each dose of VISTIDE you must also take a course of probenecid tablets. Two grams of probenecid are taken 3 hours before the VISTIDE dose, and 1 gram is taken at 2 hours and again at 8 hours after completion of the VISTIDE infusion (total dose of probenecid is 4 grams). Probenecid is only taken on the same day that VISTIDE is given.

Take these tablets with or straight after food with a full glass of water.

This may help reduce the possibility of stomach upset.

Why is normal saline given with VISTIDE?

Normal saline is given with VISTIDE, to reduce the risk of kidney damage. One litre of normal saline is given intravenously over one hour, immediately before each VISTIDE infusion. Your doctor may decide to give you a second litre of saline, and this would be given over 1 to 3 hours, starting at the same time as the VISTIDE infusion or immediately after the VISTIDE infusion. Your doctor may also instruct you to drink plenty of fluids.

Children

VISTIDE has not been studied in children, and therefore VISTIDE should not be used in children.

How is VISTIDE prepared and given?

VISTIDE will be prepared by your pharmacist or healthcare professional before use. Your dose of VISTIDE will be added to an infusion bag containing 100 mL of normal saline solution. The entire bag contents will be infused intravenously into you at a constant rate over one hour using a standard infusion pump.

If you are given too much (overdose)

The symptoms of being given too much VISTIDE may include the effects listed under the heading, "Side effects" in this leaflet.

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have been given too much VISTIDE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep the telephone numbers for these services handy. Have the VISTIDE pack or this leaflet available to give details if needed.

While you are using VISTIDE injection

Things you must do

Tell your doctor immediately if you become pregnant during or after treatment with VISTIDE.

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are being treated with VISTIDE.

Tell all doctors, dentists and pharmacists who are treating you that you are being treated with VISTIDE.

Things you must not do

Do not take any other medication unless your doctor is aware of it.

Side effects

Check with your doctor as soon as possible if you have any concerns while being treated with VISTIDE, even if you do not think the concerns are connected with the medicine or are not listed in this leaflet.

Like other medicines, VISTIDE can cause side effects. Some may be serious and need medical attention.

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

The major side effect of VISTIDE is damage to the kidneys.

Tell your doctor if you notice any of the following:

- weakness and fatigue
- hair loss
- headache
- nausea and/or vomiting
- fever
- chills
- rash

VISTIDE can also cause protein in the urine, low white blood cell count and an increase in serum creatinine that may indicate kidney damage.

Be careful driving or operating machinery until you know how VISTIDE affects you. Discuss this with your doctor and ask for their recommendation.

Some people may get other side effects during or after being treated with VISTIDE.

Tell your doctor if you notice any other effects.
Do not be alarmed by this list of possible side effects. You may not experience any of them.

After treatment with VISTIDE

Storage

VISTIDE will normally be stored in a hospital or doctor's surgery. It should be stored in its original packaging in a cool, dry place where the temperature stays below 25°C.

Product description

What it looks like

VISTIDE concentrated solution for injection comes in single-use glass vials, and requires dilution with normal saline before use. It is a clear, colourless solution.

Ingredients

The active ingredient in VISTIDE is cidofovir. Each vial contains 375 mg of anhydrous cidofovir in 5 mL of aqueous solution.

VISTIDE also contains water for injections, sodium hydroxide and hydrochloric acid.

Identification

VISTIDE can be identified by the Australian Registration Number that appears on the carton: AUST R 63050.

Supplier

VISTIDE is supplied in Australia by:

Gilead Sciences
Pty Ltd Level 6, 417 St Kilda Road
Melbourne, Victoria 3004

This leaflet was revised in 3 September 2013.