

FOSCAVIR® INJECTION

Foscarnet sodium.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions people ask about Foscavir. It does not contain all the information that is known about Foscavir.

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

All medicines have risks and benefits. Your doctor will have weighed the risks of you being given Foscavir 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 with the medicine.

You may need to read it again.

What is FOSCAVIR used for

Foscavir is used to treat infections caused by two viruses, Cytomegalovirus (CMV) and Herpes simplex virus (HSV).

These viruses infect different parts of the body and are most serious if your body's natural defences to fight disease are low (immunocompromised).

Your doctor will have explained what type of infection you have and where it is.

Foscavir belongs to a group of medicines called antivirals. It is injected into the body where it interferes with the way viral cells reproduce themselves and stops them increasing in number.

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

Your doctor may prescribe this medicine for another use.

Foscavir is not addictive.

It is only available with a doctor's prescription.

There is not enough information to recommend the use of Foscavir in children.

Before you are given FOSCAVIR

When you must not be given it

Do not use Foscavir if you have an allergy to:

- foscarnet
- any of the ingredients listed at the end of this leaflet.

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 of the skin

Foscavir should not be given to children.

Safety and effectiveness in children have not been established.

You must not be given Foscavir while you are on haemodialysis.

There is insufficient information on the use of Foscavir in patients undergoing haemodialysis.

If you are not sure whether you should be given Foscavir, talk to your doctor or nurse or pharmacist.

Before you start to use it

Tell your doctor before you are given Foscavir if you are pregnant, intend to become pregnant, are breastfeeding or intend to breastfeed.

- Foscavir is not recommended during pregnancy.
- Trying to become pregnant during Foscavir therapy is not recommended so you should use effective contraception methods.
- Men treated with Foscavir should not father a child during or up to 6 months after therapy.
- Do not have Foscavir if you are breastfeeding.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- any kidney disease or impairment
- low calcium or magnesium levels in your blood
- the need to control your sodium intake.

It may not be safe for you to use Foscavir if you have these conditions. Your doctor may do blood and urine tests before and during your treatment with Foscavir. This is to check how well your kidneys are working and the level of minerals in your blood.

Taking other medicines

Tell your doctor if you are taking any other medicines, including

any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Foscavir may interfere with each other. These include:

- certain medicines used to treat infections such as intravenous pentamidine, amphotericin, aminoglycoside antibiotics (e.g. gentamicin, streptomycin) or aciclovir.
- protease inhibitors (e.g. ritonavir, saquinavir)
- certain diuretics which are used to help reduce fluid and treat blood pressure such as frusemide
- ciclosporin, methotrexate or tacrolimus used to help prevent transplant rejection

These medicines may be affected by Foscavir or may affect how well it works.

Your doctor or pharmacist or nurse has more information on medicines to be careful with or avoid while being given this medicine.

How is FOSCAVIR given

Foscavir will be diluted with glucose 5% or normal saline, then injected slowly into a vein in your arm or leg by your doctor or nurse.

If you are in hospital, it may be injected into a major vein where it does not need to be diluted.

The dosage you will be given will depend on your body size, the infection you are being treated for, and how well your kidneys work.

How long to have it for

The initial course of treatment is over 2-3 weeks.

If you are being given Foscavir for CMV retinitis there will be two stages to your treatment.

If you are being given Foscavir to treat Herpes Simplex virus, there is only one stage to treatment.

If you forget to have Foscavir

If you think you have missed a dose, talk to your doctor straight away.

In case of overdose

If you take too much (overdose)

The doctor giving you Foscavir will be experienced in its use, so it is unlikely that you will be given an overdose.

However, if you are particularly sensitive to Foscavir, or you are given too much you may get tingling or a numb feeling like "pins and needles", dizziness, fits or seizures.

While you are given FOSCAVIR

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Foscavir.

Tell any other doctors, dentists and pharmacists who treat you that you are being given this medicine.

Drink plenty of water while you are being given Foscavir.

You may notice changes in the frequency or amount of urine while you are on Foscavir treatment. Drinking plenty of water makes kidney problems such as these less likely. Any problems with your kidneys will usually return to normal when treatment is stopped.

Keep any appointments with your doctor.

Your doctor will want to monitor how this medicine is working and

check for any side effects. They may do blood and urine tests to check how well your kidneys are working and the level of minerals in your blood.

Keep Foscavir solution and your urine away from your skin.

Foscavir is very irritating to the skin. As most of the drug is removed from the body in your urine, you should take special care to wash and dry yourself well after going to the toilet.

If you get Foscavir solution on your skin or in your eyes by mistake, rinse your skin or wash your eyes straight away with water.

Things to be careful of

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

This medicine may cause dizziness, tiredness and fits or seizures in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or nurse or pharmacist as soon as possible if you do not feel well while you are being given Foscavir.

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

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

Tell your doctor or nurse if you notice any of the following and they worry you:

- feeling or being sick
- diarrhoea or constipation
- stomach pain
- indigestion
- feeling weak or tired

- headache
- hives
- skin rash or itching
- genital discomfort and sores
- decreased appetite
- high temperature or chills
- signs of other infections
- changes in how you feel. This may include feeling depressed, confused, anxious, nervous, agitated or aggressive.
- problems with your co-ordination
- reduced feeling in the skin
- increased thirst and dry mouth
- generally feeling unwell
- muscle problems. These include changes that are shown in blood tests and painful, sore, weak or twitching muscles.
- swelling due to fluid build up in the feet or legs or other parts of the body
- lower levels of white blood cells. The signs include infections, high temperature (fever) and changes in blood test results.
- changes to red blood cells (shown in blood tests). This may make you feel tired or look pale.
- changes in how well your liver is working (shown in blood tests)
- low levels of platelets in your blood. This may make you bruise more easily.
- shaking (tremors)
- high blood pressure (often you only know this if it is measured)
- reduction in how well your pancreas is working (shown in blood tests)
- pathological alteration of the brain (encephalopathy)
- swelling, pain or inflammation at injection site
- inflammation of the oesophagus. This may be painful

These can be mild to severe side effects.

Tell your doctor or nurse immediately if you notice any of the following:

- Signs of an allergic reaction which 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 of the skin
- Severe skin reactions that may include:
 - skin lesions or sores
 - red or purple rash that rapidly spreads
 - blisters of the skin and mucous membranes
 - swelling of the lips, face or throat
- fast, slow, pounding or irregular heart beats or a change in rhythm e.g. Torsade de pointes (tests such as an ECG will also show changes in how well your heart is working)
- tingling or numb feeling like "pins and needles"
- severe pain in your abdomen (stomach area)
- swelling and redness along a vein, which may be due to a blood clot
- vomiting blood or material that looks like coffee grounds
- blood in the stools or black bowel motions
- feeling dizzy. This may be due to low blood pressure.
- fits or seizures
- a change in the colour or the amount of urine you produce, or pain when urinating. You may feel a pain in your lower back.
- changes in how well your kidneys are working (shown in blood tests)
- an imbalance of salts and minerals in your blood. The signs include weakness, cramps, thirst, tingling or itching of the skin and twitching of muscles.

- too much acid in the blood. This may make you breathe more quickly.

These may be serious side effects. You may need urgent medical attention.

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

Other side effects not listed above may occur in some people.

After using FOSCAVIR

Storage

Foscavir is stored in the pharmacy or ward. It is kept in a cool dry place where the temperature stays below 30 degrees Celsius.

Disposal

Any Foscavir solution that is not used will be disposed of in a safe manner by your doctor, nurse or pharmacist.

Product description

What it looks like

Foscavir solution for injection is a clear, colourless solution containing foscarnet sodium 24 mg/mL as the active ingredient.

It comes in bottles of 250 mL.

Ingredients

In addition Foscavir contains the following inactive ingredients:

- Hydrochloric acid
- Water for Injections

Sponsor

Foscavir is supplied in Australia by:

Link Medical Products Pty Ltd
5 Apollo St
Warriewood NSW 2102

Australian Registration Number
Foscavir: AUST R 37310

This leaflet was prepared in October
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