

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using FOSCAVIR?

FOSCAVIR contains the active ingredient foscarnet sodium. Foscavir is used to treat infections caused by two viruses, Cytomegalovirus (CMV) and Herpes simplex virus (HSV).

For more information, see Section [1. Why am I using FOSCAVIR?](#) in the full CMI.

2. What should I know before I use FOSCAVIR?

Do not use if you have ever had an allergic reaction to foscarnet sodium or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use FOSCAVIR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Foscavir and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use FOSCAVIR?

- Foscavir is diluted, then injected slowly into a vein in your arm or leg by a 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 initial course of treatment is over 2-3 weeks. For CMV retinitis there will be two stages to your treatment. To treat Herpes Simplex virus, there is only one stage to treatment.

More instructions can be found in Section [4. How do I use FOSCAVIR?](#) in the full CMI.

5. What should I know while using FOSCAVIR?

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| Things you must do | <ul style="list-style-type: none">• Tell your doctor, dentist or pharmacist straight away that you are taking Foscavir if you are about to be started on any new medicine.• Tell any other doctors, dentists and pharmacists who treat you that you are using Foscavir.• Drink plenty of water while you are being given Foscavir. |
| Driving or using machines | <ul style="list-style-type: none">• Foscavir 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.• Be careful before you drive or use any machines or tools until you know how Foscavir affects you. |
| Looking after your medicine | <ul style="list-style-type: none">• Store Foscavir below 25°C, in a cool, dry place. |

For more information, see Section [5. What should I know while using FOSCAVIR?](#) in the full CMI.

6. Are there any side effects?

If you get any of the following side effects, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital: shortness of breath, wheezing or difficulty breathing, swelling of the face, tongue or other parts of the body.

Tell your doctor or nurse if you have any of the following and they worry you: feeling or being sick, diarrhoea or constipation, stomach pain, indigestion, inflammation of the oesophagus – maybe painful. Feeling weak or tired, headache, decreased appetite, swelling due to fluid build up in the feet or legs or other parts of the body, swelling, pain or inflammation at injection site, generally feeling unwell. Genital discomfort and sores. Hives, skin rash or itching. High temperature or chills, signs of other infections. Feeling depressed, confused, anxious, nervous, agitated or aggressive. Co-ordination problems, reduced feeling in the skin, pathological alteration of the brain, shaking (tremors). Increased thirst and dry mouth. Painful, sore, weak or twitching muscles. Changes in blood test results, infections, high temperature (fever) and, feeling tired or looking pale. Bruising more easily. High blood pressure.

Tell your doctor or nurse immediately if you notice any of the following: Rash, itching or hives of the skin. 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. Tingling or numb feeling, fits or seizures. Severe pain in your abdomen, vomiting blood or material that looks like coffee grounds, blood in the stools or black bowel motions. Swelling and redness along a vein, feeling dizzy. A change in the colour or the amount of urine you produce, or pain when urinating – maybe with lower back pain. Weakness, cramps, thirst, tingling or itching of the skin and twitching of muscles, rapid breathing.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FOSCAVIR®

Active ingredient: *foscarnet sodium*

Consumer Medicine Information (CMI)

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. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Foscavir.**

Where to find information in this leaflet:

- [1. Why am I using FOSCAVIR?](#)
- [2. What should I know before I use FOSCAVIR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use FOSCAVIR?](#)
- [5. What should I know while using FOSCAVIR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using FOSCAVIR?

Foscavir contains the active ingredient foscarnet sodium. 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.

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 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.

2. What should I know before I use FOSCAVIR?

Warnings

Do not use Foscavir if:

- you are allergic to foscarnet sodium or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- 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.

Check with your doctor if you:

- have or have had any other 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.

- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Foscavir.

4. How do I use FOSCAVIR?

How much is 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.

If you use too much FOSCAVIR

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. If you experience these symptoms, tell your doctor as soon as possible and your doctor will give you the appropriate treatment.

5. What should I know while using FOSCAVIR?

Things you must do

- Tell any other doctors, dentists and pharmacists who treat you that you are using Foscavir.
- Tell your doctor, dentist or pharmacist straight away that you are taking Foscavir if you are about to be started on any new 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Foscavir affects you.

Foscavir 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.

Looking after your medicine

Foscavir is stored in the pharmacy or ward. It is kept in a cool, dry place where the temperature stays below 25 degrees Celsius.

Getting rid of any unwanted medicine

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

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
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| <p>Gut and digestion-related:</p> <ul style="list-style-type: none">• feeling or being sick• diarrhoea or constipation• stomach pain• indigestion• inflammation of the oesophagus. This may be painful. <p>Other:</p> <ul style="list-style-type: none">• feeling weak or tired• headache• swelling due to fluid build up in the feet or legs or other parts of the body• swelling, pain or inflammation at injection site• generally feeling unwell <p>Reproductive system:</p> | <p>Tell your doctor or nurse if you have any of these less serious side effects and they worry you.</p> |

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| <ul style="list-style-type: none"> genital discomfort and sores <p>Skin:</p> <ul style="list-style-type: none"> hives skin rash or itching <p>Signs of infections such as:</p> <ul style="list-style-type: none"> high temperature or chills signs of other infections <p>Mood related:</p> <ul style="list-style-type: none"> changes in how you feel. This may include feeling depressed, confused, anxious, nervous, agitated or aggressive. <p>Nervous system:</p> <ul style="list-style-type: none"> problems with your co-ordination reduced feeling in the skin pathological alteration of the brain (encephalopathy) shaking (tremors) <p>Metabolism related:</p> <ul style="list-style-type: none"> increased thirst and dry mouth decreased appetite <p>Muscle related:</p> <ul style="list-style-type: none"> muscle problems. These include changes that are shown in blood tests and painful, sore, weak or twitching muscles. <p>Blood related:</p> <ul style="list-style-type: none"> 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. reduction in how well your pancreas is working (shown in blood tests) <p>Circulatory system:</p> <ul style="list-style-type: none"> high blood pressure (often you only know this if it is measured) | |
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Serious side effects

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

| Serious side effects | What to do |
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| <p>Signs of a sudden life-threatening allergic reaction:</p> <ul style="list-style-type: none"> shortness of breath wheezing or difficulty breathing swelling of the face, lips, tongue, or other parts of the body <p>Signs of an allergic reaction such as:</p> <ul style="list-style-type: none"> rash, itching or hives of the skin <p>Skin:</p> <ul style="list-style-type: none"> 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 <p>Heart related:</p> <ul style="list-style-type: none"> 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) <p>Nervous system:</p> <ul style="list-style-type: none"> tingling or numb feeling like "pins and needles" fits or seizures <p>Gut and digestion-related:</p> <ul style="list-style-type: none"> severe pain in your abdomen (stomach area) vomiting blood or material that looks like coffee grounds blood in the stools or black bowel motions <p>Circulatory system:</p> <ul style="list-style-type: none"> swelling and redness along a vein, which may be due to a blood clot feeling dizzy. This may be due to low blood pressure. <p>Urinary system:</p> <ul style="list-style-type: none"> 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. | <p>Tell your doctor or nurse immediately or go straight to the Emergency Department at your nearest hospital if you notice any of these life-threatening side effects.</p> <p>Tell your doctor or nurse straight away if you notice any of these serious side effects.</p> |
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| <ul style="list-style-type: none"> changes in how well your kidneys are working (shown in blood tests) <p>Metabolism related:</p> <ul style="list-style-type: none"> 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. | |
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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FOSCAVIR contains

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| Active ingredient (main ingredient) | foscarnet sodium |
| Other ingredients (inactive ingredients) | hydrochloric acid water for injections |

Do not take this medicine if you are allergic to any of these ingredients.

What FOSCAVIR 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. (AUST R 37310).

Who distributes FOSCAVIR

Link Medical Products Pty Ltd
5 Apollo St
Warriewood NSW 2102