

Package leaflet: Information for the user
Foscavir[®] 24 mg/ml Solution for Infusion
foscarnet

Read all of this leaflet carefully before you start having this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Foscavir is and what it is used for
2. What you need to know before you have Foscavir
3. How to have Foscavir
4. Possible side effects
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1. What Foscavir is and what it is used for

Foscavir contains a medicine called foscarnet. This belongs to a group of medicines called anti-virals. It works by stopping viruses from multiplying in number.

Foscavir is used to treat the following infections that are caused by viruses:

- An eye infection caused by a virus in people with AIDS. The virus is called cytomegalovirus (CMV) and the infection is known as CMV retinitis. Foscavir stops the infection from getting worse but it cannot repair the damage that has already happened.
- Herpes Simplex Virus (HSV). Foscavir is given to people with HSV who have a weakened immune system. It is given to people who have not got better from HSV after having a medicine called aciclovir.

2. What you need to know before you have Foscavir

Do not have Foscavir:

- If you are allergic (hypersensitive) to foscarnet or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, talk to your doctor or nurse before having Foscavir.

Warnings and precautions

Talk to your doctor or nurse before you have Foscavir.

Check with your doctor or nurse before having Foscavir if:

- You have problems with your kidneys.
- You have problems with your heart.

If you are not sure if this applies to you, talk to your doctor or nurse before having Foscavir.

Other medicines and Foscavir

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Foscavir can affect the way some medicines work and some medicines can have an effect on Foscavir.

In particular, tell your doctor or nurse if you are already having any of the following medicines:

- Pentamidine (for infections).
- Amphotericin B (for fungal infections).
- Aciclovir (for viral infections).
- Antibiotics called aminoglycosides, such as gentamicin and streptomycin (for infections).
- Ciclosporin A, methotrexate or tacrolimus (used to suppress the immune system).
- Medicines called protease inhibitors, such as ritonavir and saquinavir.
- Laxatives.
- Quinidine, amiodarone, sotalol or any other medicines which may affect your heart rate or rhythm.
- Tranquilisers (neuroleptics).

Pregnancy and breast-feeding

- 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 breast-feeding.

Driving and using machines

Foscavir may affect you being able to drive or use tools or machines. Talk to your doctor before you do any of these activities.

Tests before and during your treatment with Foscavir

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.

Foscavir contains sodium

The maximum recommended daily dose of this medicinal product contains 2.75 g sodium (found in table salt). This is equivalent to 138% of the adult recommended maximum daily dietary intake for sodium.

Talk to your pharmacist or doctor if you need Foscavir on a daily basis for a prolonged period of time, especially if you have been advised to follow a low salt diet.

3. How to have Foscavir

- Foscavir will be given to you by a doctor or nurse. It will be given to you as an infusion (drip) into a vein. It may be given into a central line in your chest if you already have one in place.
- Each infusion will take at least 1 hour. Do not interfere with your drip during the infusion.

- The amount of Foscavir that you are given depends on how well your kidneys are working. It also depends on your weight.
- It is important to have plenty of fluid with the infusion. This will help to prevent kidney problems. If you need fluid, the doctor or nurse will give it to you at the same time as Foscavir.

Having Foscavir for CMV retinitis

If you are having Foscavir for CMV retinitis, there will be two stages to your treatment. The first stage is called induction therapy and the second stage is called maintenance therapy.

Induction therapy

- During induction therapy, you will be given an infusion every 8 hours. This will usually happen for 2 or 3 weeks.
- The usual dose for induction therapy is 60 mg of Foscavir for every kilogram that you weigh (60 mg/kg).
- Your doctor will tell you when you are ready to change to maintenance therapy.

Maintenance therapy

- During maintenance therapy, you will be given an infusion once a day.
- The usual dose for maintenance therapy is 60 to 120 mg of Foscavir for every kilogram that you weigh (60 to 120 mg/kg).

Your doctor will tell you if you need to have more or less Foscavir and how often you should have it. This is so that you have the dose that is right for you.

Sometimes your doctor may ask you to have a medicine called ganciclovir as well. This is to make sure that you have the treatment that is right for you.

Having Foscavir for Herpes Simplex Virus

- If you are being given Foscavir to treat Herpes Simplex Virus, there is only one stage.
- You will be given an infusion every 8 hours.
- Your wounds (lesions) may start to heal after about 1 week. However, you may need to keep having Foscavir for 2 to 3 weeks or until your wounds have healed.
- The usual dose is 40 mg of Foscavir for every kilogram that you weigh (40 mg/kg).

Personal hygiene

Wash your genitals carefully after passing water (urine). This will help to prevent any sores from developing.

If you get Foscavir solution on your skin or in your eyes

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

If you think you have been given too much Foscavir

If you think you have been given too much Foscavir, talk to your doctor straight away.

If you forget to have Foscavir

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

4. Possible side effects

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

Some side effects can be serious and need immediate medical attention:

- Severe allergic reactions including a fall in blood pressure, shock and swelling of the skin (angioedema). They are known as hypersensitivity, anaphylactic or anaphylactoid reactions.
- Severe skin rashes. These types of rashes can be associated with redness, swelling, and blisters of the skin, mouth, throat, eyes and other places inside the body and can sometimes result in death. They are called erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis.

If you get any of the above, tell your doctor straight away or go to the nearest emergency unit.

Other side effects include:

Very common (affects more than 1 in 10 people)

- Loss of appetite.
- Diarrhoea.
- Feeling or being sick.
- Feeling weak or tired.
- High temperature or chills.
- Feeling dizzy.
- Headache.
- Pins and needles.
- Skin rash.
- Changes in how well your kidneys are working (shown in blood tests).
- Low levels of white blood cells. The signs include infections and high temperature (fever).
- Changes to red blood cells (shown in blood tests). This may make you feel tired or look pale.
- 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.

Common (affects less than 1 in 10 people)

- Pain in the tummy (abdomen), constipation, indigestion or gastrointestinal bleeding.
- Inflamed pancreas (pancreatitis) or changes in how well your pancreas is working. The signs include severe stomach pain and there may be changes that are shown in blood tests.
- Feeling anxious, nervous, depressed, agitated, aggressive or confused.
- Problems with your co-ordination.
- Fits (convulsions).
- Reduced feeling in the skin.
- Itchy skin.
- Generally feeling unwell.
- Swelling of the feet and legs.
- Pounding heart beat (palpitations) or change in rhythm e.g. torsade de pointes or tachycardia.
- High blood pressure.

- Low blood pressure. This may make you feel dizzy.
- Changes in tests that show how well your heart is working (ECGs).
- Muscle problems. These include changes that are shown in blood tests and painful, sore, weak or twitching muscles.
- Shaking (tremors).
- Nerve damage that may cause changes in sensation or muscle weakness (neuropathy).
- Swelling, pain and redness along a vein or where the injection needle is inserted.
- Genital sores.
- 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.
- Infection of the blood.
- Kidney problems. These include pain in your kidneys (you may feel this in your lower back) and kidney failure. There may be changes that are shown in blood or water (urine) tests.
- Pain when you pass water (urine).
- Passing water (urine) more often than normal. Rarely, you may also feel very thirsty or dehydrated.
- Pain in your chest.

Uncommon (affects less than 1 in 100 people)

- An itchy rash (urticaria).
- Too much acid in the blood. This may make you breathe more quickly.

The following side effects have also been reported (frequency not known)

- Unusual heart beat.
- An ulcer in your oesophagus (the passage where food travels from the throat to the stomach). This may be painful.
- Severe muscle problems with a breakdown of your muscle tissue (rhabdomyolysis). The signs include abnormal urine colour and severe muscle weakness, tenderness or stiffness.
- Blood in your water (urine).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Foscovir

- 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. The expiry date refers to the last day of that month.
- Do not store unopened bottles of Foscovir above 25°C. Do not put them in the fridge.
- Foscovir may be mixed with another liquid by a pharmacist. This is to give you a medicine ready to use. The pharmacist will tell you how to store it and when to use it by.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Foscavir contains

- The active substance is foscarnet. There is 24 mg of foscarnet in each millilitre (ml) of solution.
- The other ingredients are water for injection and hydrochloric acid (E507).

What Foscavir looks like and contents of the pack

Foscavir is a sterile solution for infusion. The solution is clear and colourless. Foscavir comes in bottles containing 250 ml.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Foscavir is held by Clinigen Healthcare Ltd., Pitcairn House, First Avenue, Burton-on-Trent, Staffordshire, DE14 2WW, UK.

Foscavir is manufactured by Fresenius Kabi Austria GmbH, Hafnerstrasse 36, A-8055 Graz, Austria.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name Foscavir
Reference number 31644/0001

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in November 2020.

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