Package leaflet: Information for the user
Foscavir®
24 mg/mL Solution for Infusion
foscarnet
M088729/06 UK
Reading all the leaflet carefully before you start having this medicine because it contains important information for you.
• Keep this leaflet. You may need to refer to it at any time.
• If you have any further questions, ask your doctor or nurse.
This medicinal product has been prescribed for you only. Do not pass it on to others. It may help people whose age or state of health are the same as yours.
• If you are in doubt about your treatment, 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.
5. How to store Foscavir.
6. Contents of the pack and other information.

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 called CMV retinitis. Foscavir stops the infection from getting any 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 if this applies to you, talk to your doctor or nurse before having Foscavir.

Warnings and precautions
Tell your doctor or nurse if you have:
• Problems with your heart.
• Problems with your kidneys. It is important to have plenty of fluid with the infusion. This will help to prevent kidney damage. 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 is usually for 2 to 3 weeks.
• The usual dose for induction therapy is 60 mg of Foscavir for every kilogram that you weigh (90 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 mg of Foscavir for every kilogram that you weigh (90 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 taking 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 genitalia carefully after passing water (urine). This will help to prevent any virus from spreading.
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 have been given too much Foscavir, talk to your doctor straight away.

If you have allergic reactions include:

• Rash (affects more than 1 in 10 people)
• Other side effects include:

1. 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 skin reactions including a fall in blood pressure, shock and swelling of all or part of the body (in angioedema). They are known as hypersensitivity, anaphylactic or anaphylactoid reactions.
• Severe skin rashes. These types of rash include 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.
• An ulcer in your oesophagus (the 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:

• Muscle weakness, tenderness or pain.
• Muscle hardening or changes that are shown in blood tests.
• Changes in how well your pancreas is working.
• Changes in how well your liver is working (shown in blood tests).

Other side effects include:

• Loss of appetite.
• Inflamed pancreas.
• Changes in sensation or muscle weakness.
• Shaking (tremors).
• Changes to red blood cells (shown in blood tests).
• Changes to white blood cells.
• Feeling or being sick.
• High temperature.
• Passing water (urine) more often than normal. Rarest.
• Infection of the blood.
• Pain in your chest.
• Swelling, pain and redness along a vein or where the injection needle is inserted.
• Muscle problems with a breakdown of your muscle tissue (rhabdomyolysis). The signs include:

• Muscle weakness, tenderness or pain.
• Muscle hardening or changes that are shown in blood tests.
• Changes in how well your liver is working (shown in blood tests).

2. Uncommon effects (less than 1 in 100 people)

• An itchy rash (urticaria).
• Muscle weakness, tenderness or pain.
• Muscle hardening or changes that are shown in blood tests.
• Changes to white blood cells.
• Feeling weak or tired.
• Unusual heart beat.
• Stiffness.
• Diarrhoea.
• Abdominal pain.
• Rash.
• Erythema multiforme.
• Epidermal necrolysis.
• Stevens-Johnson syndrome and toxic epidermal necrolysis.
• Itchy skin.
• Fever.
• Muscle rashes.
• Fever.
• Muscle weakness, tenderness or pain.
• Muscle hardening or changes that are shown in blood tests.
• Changes in how well your liver is working (shown in blood tests).
• Changes in how well your kidneys are working (shown in blood tests). This may make you feel tired or weak and may make you have a fall in blood pressure, shock and swelling of all or part of the body (in angioedema). They are known as hypersensitivity, anaphylactic or anaphylactoid reactions.
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• An ulcer in your oesophagus (the food travels from the throat to the stomach). This may be painful.
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• Muscle weakness, tenderness or pain.
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• Changes in how well your pancreas is working.
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• Severe muscle problems with a breakdown of your muscle tissue (rhabdomyolysis). The signs include:

• Muscle weakness, tenderness or pain.
• Muscle hardening or changes that are shown in blood tests.
• Changes in how well your pancreas is working.
• Changes in how well your liver is working (shown in blood tests).

3. How to store Foscavir

• Keep this medicine out of the sight and reach of children.
• Do not use this medicine after the expiry date on the label. The expiry date refers to the last day of that month.
• Do not store unopened bottles of Foscavir above 30°C. Do not put them in the fridge.
• Foscavir may be mixed with another liquid by the pharmacist. This may give you a medicine ready to use. The pharmacist will tell you how to store it and when to use it.
• 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.

4. Contents of the pack and other information

What Foscavir contains

The active substance is foscarnet. There is 24 mg of foscarnet in each milliliter (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 Marketing

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

Foscavir is manufactured by Fresenius Kabi Australia GmbH, Hafenstrasse 36, A-8050 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 Institute of Blind People.

This leaflet was last revised in January 2019.

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