

Package leaflet: Information for the user

Virafosc 24 mg/ml solution for infusion foscarnet sodium hexahydrate

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

Virafosc contains the active substance foscarnet. It belongs to a class of medicines called antivirals and it works by stopping viruses from multiplying in number.

Virafosc is used in adults to treat the following infections that are caused by a virus called cytomegalovirus (CMV):

- An eye infection caused by a virus in people with AIDS. The infection is known as CMV retinitis.
- CMV infections of the organs in the gastrointestinal tract in people with AIDS.
- CMV viraemia or disease. Virafosc is given to people with CMV infection after having a bone marrow transplant. A bone marrow transplant is also known medically as a haematopoietic stem cell transplant (HSCT). The infection can cause disease in any organ and can sometimes be detected before the patient starts to suffer signs of illness. This is called CMV viraemia.

Virafosc is also used to treat the infections caused by a virus called Herpes Simplex Virus (HSV). It is given to people with HSV who have a weakened immune system and have not got better from HSV after having a medicine called aciclovir.

2. What you need to know before you have Virafosc

Do not have Virafosc:

- 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 Virafosc.

Warnings and precautions

Talk to your doctor or nurse before you have Virafosc if:

- You have problems with your kidneys.
- You have problems with your heart.
- You need haemodialysis (your blood is dialysed).

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

Children and adolescents

The safety and efficacy of foscarnet in children have not been established.

Other medicines and Virafosc

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 Virafosc can affect the way some medicines work and some medicines can have an effect on foscarnet.

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.
- Quinidine, amiodarone, sotalol or any other medicines which may affect your heart rate or rhythm.
- Medicines used to reduce tension or anxiety (neuroleptics).

Pregnancy and breast-feeding

Women of childbearing potential/contraception in males and females

- Trying to become pregnant during Virafosc therapy is not recommended. You should use effective contraception methods during treatment and for up to 6 months after completion of treatment.
- Men treated with Virafosc should not father a child during treatment and for up to 6 months after completion of treatment.

Pregnancy

- There is insufficient data about the safety of Virafosc during pregnancy. Use of this medicine is not recommended during pregnancy and it should only be administered during pregnancy when this is strictly necessary, no safer alternatives are available and treatment cannot be postponed.

Breast-feeding

- Do not have Virafosc if you are breast-feeding. It is unknown whether this medicine is excreted in human milk.
- It is recommended that women infected with HIV avoid breastfeeding so as to prevent the transmission of HIV.

Driving and using machines

Virafosc may affect you being able to drive or use tools or machines. This is because it may cause side effects such as dizziness or epileptic seizures which may affect your ability to react. Read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are unsure about anything.

Tests before and during your treatment with Virafosc

Your doctor may do blood and urine tests before and during your treatment with Virafosc. This is to check how well your kidneys are working and the level of minerals in your blood.

Virafosc 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 Virafosc 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 Virafosc

- Virafosc 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 Virafosc 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 Virafosc.

Having Virafosc for CMV infections

If you are having Virafosc for CMV infections, 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 or 12 hours. This will usually happen for 2 or 3 weeks.
- The usual dose for induction therapy is 60 or 90 mg of Virafosc for every kilogram that you weigh (60 or 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 90 to 120 mg of Virafosc for every kilogram that you weigh (90 to 120 mg/kg).

Your doctor will tell you if you need to have more or less Virafosc 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 Virafosc for Herpes Simplex Virus

- If you are being given Virafosc 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 Virafosc for 2 to 3 weeks or until your wounds have healed.
- The usual dose is 40 mg of Virafosc 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 Virafosc solution on your skin or in your eyes

If you get Virafosc 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 Virafosc

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

If you forget to have Virafosc

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.
- Fever or chills.
- Feeling dizzy.
- Headache.
- Pins and needles.
- Skin rash.
- Changes in how well your kidneys are working (renal impairment - shown in blood tests).
- Low levels of white blood cells. The signs include infections and high temperature (fever).
- Low levels of 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, including 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.
- Kidney damage (glomerulonephritis). You experience puffiness in your face or ankles, blood in your water (urine), brown-coloured urine or passing urine less often than normal.
- Other kidney problems may also occur in blood or water (urine) tests e.g. nephrotic syndrome, renal tubular disorder.

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

- Mental status changes and brain disorder characterised, for example, by seizures and decreased consciousness (encephalopathy).
- Heart rhythm abnormalities, such as disorders of the ventricular rhythm (ventricular arrhythmia) or a fast, irregular heart beat or fainting which could be a symptom of a life-threatening condition called torsade de pointes.
- 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.
- Kidney damage, such as pain in your kidneys (you may feel this in your lower back), presence of blood in your water (urine), tubular acidosis or necrosis, crystal nephropathy (the formation of crystals in the kidneys).

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 national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Virafosc

- 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 carton after EXP. The expiry date refers to the last day of that month.
- Store below 25°C. Do not refrigerate or freeze.
- This medicine can be mixed with 5 % glucose or saline to enable the correct dosing for you. This will be handled by the healthcare staff.

6. Contents of the pack and other information

What Virafosc contains

- The active substance is foscarnet (as sodium hexahydrate). The medicine has 24 mg of foscarnet in each millilitre (ml) of solution.

- The other ingredients are water for injections and hydrochloric acid (E507).

What Virafosc looks like and contents of the pack

The solution is clear and colourless. Virafosc comes in glass bottles sealed with a rubber stopper and plastic flip-off lid. Each bottle contains 250 ml solution.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in 2022-11-29.

Detailed information on this medicine is available on the website of {name of Member State Agency (link)}

The following information is intended for healthcare professionals only:

When peripheral veins are used, the solution of foscarnet 24 mg/ml must be diluted. Individually dispensed doses of foscarnet should be aseptically transferred to plastic infusion bags and diluted with equal parts of 5% glucose or physiological saline to a concentration of 12 mg/ml by the hospital pharmacy. The physico-chemical stability of foscarnet and dilutions in PVC bags is 7 days. However, diluted solutions should be refrigerated and storage restricted to 24 hours.

Each bottle of foscarnet should only be used to treat one patient with a single infusion.

Accidental skin and eye contact with the foscarnet sodium solution may cause local irritation and burning sensation. If accidental contact occurs, the exposed area should be rinsed with water.

If foscarnet refrigerated or exposed to temperatures below freezing point precipitation may occur. By keeping the bottle at room temperature with repeated shaking, the precipitate can be brought into solution again.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.