

PACKAGE LEAFLET

Package leaflet: Information for the user

Foscarnet sodium hexahydrate Tillomed 24 mg/ml solution for infusion

foscarnet sodium hexahydrate

Read all of this leaflet carefully before you start using 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, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What Foscarnet Tillomed is and what it is used for
2. What you need to know before you use Foscarnet Tillomed
3. How to use Foscarnet Tillomed
4. Possible side effects
5. How to store Foscarnet Tillomed
6. Contents of the pack and further information

1. What Foscarnet Tillomed is and what it is used for

Foscarnet Tillomed contains a medicine called foscarnet sodium hexahydrate. This belongs to a group of medicines called antivirals. It works by stopping viruses from multiplying in number.

Foscarnet Tillomed is used to treat the following infections in AIDS patients:

- A life-threatening or vision threatening eye infection called CMV retinitis caused by a virus in people with AIDS which leads to a loss of vision and eventually blindness. The virus is called cytomegalovirus (CMV) and the infection is known as CMV retinitis. Foscarnet Tillomed stops the infection from getting worse but it cannot repair the damage that has already happened.
- Herpes Simplex Virus (HSV). Foscarnet Tillomed 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 use Foscarnet Tillomed

Do not use Foscarnet Tillomed :

- if you are allergic (hypersensitive) to foscarnet sodium hexahydrate 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 you are given foscarnet.

Warnings and precautions

Talk to your doctor or nurse before using Foscarnet Tillomed 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 you are given foscarnet.

Children and adolescents

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

Other medicines and Foscarnet Tillomed

Tell your doctor or pharmacist 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.

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

- Pentamidine (for infections)
- Amphotericin B (for fungal infections)
- Acyclovir (for viral infections)
- Antibiotics called aminoglycosides, such as gentamicin and streptomycin (for infections)
- Cyclosporine 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, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Foscarnet Tillomed is not recommended during pregnancy.

Trying to become pregnant during Foscarnet Tillomed therapy is not recommended so you should use effective contraception methods during and up to 6 months after therapy.

Men treated with Foscarnet Tillomed should not father a child during or up to 6 months after therapy.

Do not use Foscarnet Tillomed if you are breastfeeding.

Driving and using machines

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

Tests before and during your treatment with Foscarnet Tillomed

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

Foscarnet Tillomed contains sodium

This medicine contains 1375 mg sodium (main component of cooking/table salt) in each 250 ml bottle. This is equivalent to 69% of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 71 ml or more daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

3. How to use Foscarnet Tillomed

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Foscarnet Tillomed 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 foscarnet 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 foscarnet.

Use of Foscarnet Tillomed for CMV infection

If you are having Foscarnet Tillomed 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 Foscarnet Tillomed for every kilogram that you weigh (60 mg/kg) three times daily (every 8 hours) or 90 mg/kg body weight twice daily (every 12 hours).
- 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 Foscarnet Tillomed for every kilogram that you weigh (90 to 120 mg/kg).

Your doctor will tell you if you need to have more or less Foscarnet Tillomed 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.

Use of Foscarnet Tillomed for Herpes Simplex Virus

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

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

Use in children and adolescents:

The safety and efficacy of Foscarnet Tillomed has not been established in children and adolescents below 18 years of age have not been established.

If you use more Foscarnet Tillomed than you should

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

If you forget to use Foscarnet Tillomed

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

If you have any further questions on the use of this medicine, ask your doctor or nurse.

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: (may affect 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: (may affect up to 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 heartbeat (palpitations) or change in rhythm e.g torsade de pointes or fast heartbeat (tachycardia)
- High blood pressure
- low blood pressure. This may make you feel dizzy
- Changes in tests that show how well your heart is working (ECG)
- 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. This includes 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
- passing water (urine) more often than normal. Rarely you may also feel very thirsty or dehydrated.
- pain in your chest

Uncommon: (may affect up to 1 in 100 people)

- An itchy rash (urticaria)
- too much acid in the blood. This may make you breathe more quickly
- Reduction of all blood cells (pancytopenia)

Not known: frequency cannot be estimated from the available data

- unusual heartbeat
- 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 pharmacist 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 HPRa pharmacovigilance Website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Foscarnet Tillomed

- 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 and bottle label after EXP. The expiry date refers to the last day of that month.
- Do not refrigerate or freeze.
- Foscarnet Tillomed should not be kept below 8°C as precipitation can occur at lower temperatures. Precipitation remains even if the infusion solution is frozen and thawed again.
- Foscarnet Tillomed can be made ready for use again if it has been accidentally stored at refrigerator temperatures or if the infusion solution has been exposed to temperatures below freezing. The bottle should then be shaken vigorously several times and kept at room temperature for 4 hours until all precipitation has completely dissolved.

After opening:

From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

After dilution:

Chemical and physical in-use stability has been demonstrated for 36 hours at 2-8°C and 20-25°C when solution is diluted from 24 mg/ml to 12 mg/ml of foscarnet sodium hexahydrate in PVC bags. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

- Do not use Foscarnet Tillomed if you notice any damage to the bottle, discolouration or other signs of deterioration.

- 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 Foscarnet Tillomed contains

- The active substance is foscarnet sodium hexahydrate.
- One ml of solution contains 24 mg foscarnet sodium hexahydrate. One 250 ml bottle contains 6000 mg foscarnet sodium hexahydrate.
- The other ingredients are hydrochloric acid, dilute for pH adjustment and water for injections.

What Foscarnet Tillomed looks like and contents of the pack

Foscarnet Tillomed is a clear, colourless solution for infusion in glass bottles. Each pack contains 1 bottle or 10 bottles of 250 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Tillomed Pharma GmbH
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12529 Schönefeld
Germany

Manufacturer¹

MIAS Pharma Limited
Suite 2, Stafford House,
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SGS Pharma Magyarország Kft.
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Hungary

¹Only actual manufacturer stated on printed leaflet

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	: Foscarnet Tillomed 24 mg / ml Infusionslösung
Czech Republic	: Foscarnet Tillomed
Denmark	: Foscarnet “Tillomed”
Estonia	: Foscarnet sodium Tillomed
Finland	: Foscarnet Tillomed 24 mg/ml infuusioneste, liuos
France	: Foscarnet Tillomed 24 mg/ml solution pour perfusion
Germany	: Foscarnet Tillomed 24 mg / ml Infusionslösung
Greece	: Foscarnet Tillomed 24 mg / ml διάλυμα για έγχυση
Ireland	: Foscarnet sodium hexahydrate Tillomed 24 mg/ml solution for infusion
Italy	: Foscarnet Tillomed
Latvia	: Foscarnet sodium Tillomed
Lithuania	: “Foscarnet Tillomed” 24 mg / ml infuzinis tirpalas
Netherland	: Foscarnet Tillomed 24 mg / ml oplossing voor infusie
Norway	: Foskarnetnatriumheksahydrat Tillomed
Poland	: Foscarnet sodium hexahydrate Tillomed
Portugal	: Foscarnet Tillomed 24 mg / ml solução para perfusão
Slovakia	: Foscarnet Tillomed 24 mg / ml infúzny roztok
Spain	: Foscarnet Tillomed 24 mg/ml solución para perfusión EFG
Sweden	: Foscarnet Tillomed 24 mg/ml infusionsvätska, lösning

This leaflet was last revised in 08/2023

The following information is intended for healthcare professionals only:

Instructions for use and handling

When infused into peripheral veins, the solution should be diluted from 24 mg/ml to 12 mg/ml of Foscarnet sodium hexahydrate before use. Individually dispensed doses of Foscarnet Tillomed should be aseptically transferred to plastic infusion bags (PVC bags) and diluted with equal parts of 9 mg/ml (0.9%) sodium chloride solution or 50 mg/ml (5%) glucose solution.

Storage and shelf-life of the medicinal product and diluted solution: see section 5.

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

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

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