PACKAGE LEAFLET: INFORMATION FOR THE USER

Fomicyt 40 mg/ml Powder for solution for infusion
Fosfomycin

Read all of this leaflet carefully before you start taking 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 pharmacist 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 pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Fomicyt is and what it is used for

Fomicyt contains the active substance fosfomycin. It belongs to a group of medicines called antibiotics. It works by killing certain types of germs (bacteria) that cause serious infectious diseases. Your doctor has decided to treat you with Fomicyt to help your body fight an infection. It is important that you receive effective treatment for this condition.

Fomicyt is used in adults, adolescents and children to treat bacterial infections of:

– the urinary tract

– the heart - sometimes called ‘endocarditis’

– the bones and joints

– the lungs called "pneumonia"

– the skin and tissues below the skin

– the central nervous system

– the abdomen

– the blood, when caused by any of the conditions listed above

2. What you need to know before you use Fomicyt

Do not use Fomicyt:

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

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Fomicyt if you suffer from one of the following disorders:

- heart problems (cardiac insufficiency), especially if digitalis medicine is taken (due to possible hypokalaemia)
- high blood pressure (hypertension)
- a certain disorder of the hormone system (hyperaldosteronism)
- high levels of blood sodium (hypernatraemia)
- fluid accumulation in the lungs (pulmonary oedema)
- kidney problems. Your doctor may need to change the dose of your medicine (see section 3 of this leaflet).
- previous episodes of diarrhea after taking or receiving any other antibiotics

Conditions you need to look out for
Fomicyt can cause serious side effects. These include allergic reactions, inflammation of the large intestine and a decreasing number of white blood cells. You must look out for certain symptoms while you are taking this medicine, to reduce the risk of any problems. See "Serious side effects" in Section 4.

Other medicines and Fomicyt
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- anticoagulants, as their ability to prevent your blood from clotting might be altered by fosfomycin and other antibiotics.

Pregnancy and breast-feeding
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 you are given this medicine.

Fosfomycin may pass to the baby in the womb or through breast milk. If you are pregnant or breast-feeding your doctor will only give you this medicine when it is clearly needed.

Driving and using machines
When Fomicyt is given, there may be side effects such as confusion and weakness. If these occur, you should not drive or operate machinery.

Important information about some of the ingredients of Fomicyt
This medicine contains 14 mmol (320 mg) sodium per 1 g fosfomycin. This is equivalent to 16 % of the recommended maximum daily dietary intake of sodium for an adult. One bottle with 2 g fosfomycin contains 28 mmol (640 mg) sodium, one bottle with 4 g fosfomycin contains 56 mmol (1280 mg) sodium and one bottle with 8 g fosfomycin contains 111 mmol (2560 mg) sodium.
This should be taken in consideration if you are on a controlled sodium diet.
While on treatment with this medicine, you should follow a low-salt diet to reduce your sodium intake.

3. How to use Fomicyt

Fomicyt is given to you into a vein (a drip) by a doctor or a nurse.

Dosage
The dose you will be given and the frequency of the dose will depend on:

– The type and severity of infection you have

– Your kidney function.

In children, it also depends on

– The child's weight

– The child's age

If you have problems with your kidneys or require dialysis, your doctor may need to reduce your dose of this medicine

Route and method of administration

For intravenous use.

Fomicyt is given to you into a vein (a drip) by a doctor or a nurse. The infusion will normally take 15 to 60 minutes, depending on your dose. Usually this medicine is given 2, 3 or 4 times a day.

Duration of treatment
Your doctor will decide how long your treatment should last depending on how fast your condition will improve. When treating bacterial infections it is important to complete the full course of treatment. Even after the fever has passed and the symptoms have abated, treatment should be continued for a few days more.

Certain infections, such as infections of the bones, may require an even longer treatment period after the symptoms have subsided.

If you are given more Fomicyt than you should
It is unlikely that your doctor or nurse will give you too much medicine. Ask them immediately if you think that you have been given too much of this medicine.

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

4. Possible side effects

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

Serious side effects

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

– Signs of a serious allergic reaction (very rare: may affect up to 1 in 10,000 people,). These may include: breathing or swallowing problems, sudden wheezing, dizziness, swelling of eyelids, face, lips or tongue, rash or itching.

– Severe and persistent diarrhea, which may be associated with abdominal pain or fever (the frequency is unknown). This may be a sign of a serious bowel inflammation. Do not take medicines against diarrhea that inhibit the bowel movements (antiperistaltics).

– Yellowing of the skin or the whites of your eyes (jaundice, the frequency is unknown). This can be an early sign of liver problems.

– Confusion, muscle twitching or abnormal heart rhythm. This could be caused by high levels of blood sodium or low levels of blood potassium (common: may affect up to 1 in 10 people).

Tell your doctor or nurse as soon as possible if you notice any of the following side effects:

– Pain, burning, redness or swelling along the vein which is used during infusion of this medicine (common: may affect up to 1 in 10 people).

– You bleed or bruise more easily or get more infections than usual. This could be because you have a low number of white blood cells or blood platelets (the frequency is unknown).

Other side effects can include:

Common side effects (may affect up to 1 in 10 people)

– Taste disturbances

Uncommon side effects (may affect up to 1 in 100 people)

– Feeling sick, vomiting, or mild diarrhea

– Headache

– High levels of blood liver enzymes, possibly associated with liver problems.

– Rash

– Feebleness

Side effects with not known frequency (frequency cannot be estimated from the available data)

– Liver problems (hepatitis),

– Itching, hives

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom
via the Yellow Card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA Pharmacovigilance, Website: www.hpra.ie

5. How to store Fomicyt

- Keep out of the reach and sight of children.
- This medicine does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the carton and label after "EXP". The expiry date refers to the last day of that month.
- After being mixed with solvent this medicine should be used immediately or stored in a refrigerator (at 2–8°C) protected from light for up to 24 hours.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Content of the pack and other information

What Fomicyt contains

The active substance is fosfomycin. Each ml of the solution for infusion contains 40 mg of fosfomycin.

- Each bottle of Fomicyt 2 g with 2.69 g of powder for solution in 50 ml solvent contains 2.64 g disodium fosfomycin, corresponding to 2 g fosfomycin and 0.64 g sodium.
- Each bottle of Fomicyt 4 g with 5.38 g of powder for solution in 100 ml solvent contains 5.28 g disodium fosfomycin, corresponding to 4 g fosfomycin and 1.28 g sodium.
- Each bottle of Fomicyt 8 g with 10.76 g of powder for solution in 200 ml solvent contains 10.56 g disodium fosfomycin, corresponding to 8 g fosfomycin and 2.56 g sodium.

The other ingredient is succinic acid.

What Fomicyt looks like and contents of the pack

This medicine is a white to cream-coloured powder for solution for infusion. The solution for infusion is clear and colourless to slightly yellowish.

It is packed in clear glass bottles (type I) with a rubber stopper (bromobutyl rubber) and pull-off cap.

Three sizes of vials are available:
- bottles with 2 g fosfomycin, each pack contains 10 bottles
- bottles with 4 g fosfomycin, each pack contains 10 bottles
- bottles with 8 g fosfomycin, each pack contains 1 or 10 bottles

Marketing Authorisation Holder and Manufacturer
INFECTOPHARM Arzneimittel und Consilium GmbH
Von-Humboldt-Str. 1, 64646 Heppenheim
Germany

Distributor in the UK
Kent Pharma UK Ltd
The Bower
4 Roundwood Avenue
Stockley Park
Uxbridge
UB11 1AF

Distributor in Ireland
Athlone Pharmaceuticals Ltd
Ballymurray
Co Roscommon
Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom (Northern Ireland):	Fomicyt 40 mg/ml Powder for solution for infusion
Italy:	InfectoFos
Poland:	InfectoFos, 40 mg/ml, proszek do sporządzania roztworu do infuzji
Ireland:	Fomicyt 40 mg/ml Powder for solution for infusion
The Netherlands:	Fomicyt 40 mg/ml Poeder voor oplossing voor infusie
Greece:	Fomicyt 40 mg/ml Κόνις για διάλυμα προς έγχυση
Sweden, Finland, Denmark, Norway:	Fosfomycin Infectopharm
Croatia:	Fomicyt 40 mg/ml prašak za otopinu za infuziju
Austria:	Fomicyt 40 mg/ml Pulver zur Herstellung einer Infusionslösung
Belgium:	Fomicyt 40 mg/ml poeder voor oplossing voor infusie/ Fomicyt 40 mg/ml Poudre pour solution pour perfusion/

	Fomicyt 40 mg/ml Pulver zur Herstellung einer Infusionslösung
Czech Republik:	Fomicyt
Hungary:	Fomicyt 40 mg/ml por oldatos infúzióhoz
Romania:	Fomicyt 40 mg/ml pulbere pentru soluție perfuzabilă
Slovakia:	Fomicyt

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The following information is intended for medical or healthcare professionals only:

Fomicyt 40 mg/ml powder for solution for infusion is for single use only and any unused solution should be discarded.

Preparation of the solution for infusion
Fomicyt must be reconstituted and diluted prior to administration.

Water for Injections and Glucose Infusion 50 mg/ml (5 %) or Glucose Infusion 100 mg/ml (10 %) may be used as solvent for the reconstitution and dilution. Sodium chloride containing solvents must not be used.

Reconstitution
Shake the vial prior to the reconstitution to loosen up the powder. Reconstitute the 2 g or 4 g vials with 20 ml and the 8 g vial with 40 ml of solvent. Shake well to dissolve. A slight degree of warming occurs when the powder is dissolved.
Caution: This intermediate solution is not for direct infusion. Withdraw the solution completely from the original vial. Transfer the withdrawn solution into an infusion bag or other suitable infusion container for further dilution as follows.

Dilution
Transfer the reconstituted contents of **2 g vials** into an infusion container with further **30 ml** of solvent.
Transfer the reconstituted contents of **4 g vials** into an infusion container with further **80 ml** of solvent.
Transfer the reconstituted contents of **8 g vials** into an infusion container with further **160 ml** of solvent.

Displacement value
The displacement values for the solutions are 1 ml for the 2 g pack size, 2 ml for the 4 g pack size and 4 ml for the 8 g pack size.
These volumes are equivalent to an increase of volume of 2 %. This has to be considered when not the entire volume of the final diluted solution is used.

Method of administration
Fomicyt is intended for intravenous use.

The duration of infusion should be at least 15 minutes for the 2 g pack size, at least 30 minutes for the 4 g pack size and at least 60 minutes for the 8 g pack size.

As damaging effects can result from inadvertent intra-arterial administration of products not specifically recommended for intra-arterial therapy, it is essential to ensure that fosfomycin is only administered into veins.

Shelf life of the solution for infusion
Chemical and physical in-use stability of the final diluted solution that has been produced under aseptic conditions has been demonstrated for 24 hours at 25°C if protected from light.

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 preparation has taken place in controlled and validated aseptic conditions.