Rx Fosfomycin for Injection

AMERICAN
FOSMOS
Injection

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 Fosfomycin is and what it is used for
2.What you need to know before you use Fosfomycin
3.How to use Fosfomycin
4.Possible side effects
5.Storage condition

1. What Fosfomycin is and what it is used for

Fosfomycin 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 Fosfomycin to help your body fight an infection. It is important that you receive effective treatment for this condition.

Fosfomycin 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 Fosfomycin

Do not use Fosfomycin:

•if you are allergic to fosfomycin

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Fosfomycin 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 Fosfomycin 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 Fosfomycin

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 Fosfomycin 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 Fosfomycin

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 Fosfomycin

Fosfomycin 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.

Fosfomycin 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 Fosfomycin 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

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

Fosfomycin 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

Fosfomycin 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.

5. **STORAGE:** Store below 25°C. Protect from light.

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