

Use of fosfomycin antibiotics restricted following EMA review

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Information on Fosfomycin antibiotics

- Fosfomycin is an antibiotic which has been used for many decades in the EU to treat a range of infections. It is given by mouth as granules (containing fosfomycin trometamol), capsules and powder for oral suspension (fosfomycin calcium), by infusion (drip) into a vein or by injection into muscle
- When given by mouth it is mainly used for treating women with uncomplicated urinary tract infections caused by bacteria that are vulnerable to fosfomycin's antibacterial effects. In some EU countries it has also been used to prevent infections associated with surgical or diagnostic procedures in the urinary tract
- Fosfomycin infusion has been authorised for treating patients of all ages with serious infections such as osteomyelitis (infection of the bone), complicated urinary tract infections, respiratory tract infections that start in hospital, meningitis and bacterial infections in the blood arising from the other infections. Fosfomycin infusion is reserved for use when other antibiotics cannot be used or are not effective
- Fosfomycin for injection into the muscle has been authorised for treating or preventing various infections including infections of the urinary and reproductive systems.

In Malta Fosfomycin antibiotics are authorised through national procedures:

Active Ingredients	Product Name	Pharmaceutical Form	Classification	Authorisation Number	MAH/license holder
Fosfomycin trometamol 5.631 gram(s)	Monuril granules for oral solutions 3g	Oral Solution	POM	AA1116/00101	Zambon Spa
Fosfomycin 3 gram(s)	Fosfoseptic granules for oral solution 3g	Granules for oral solution	POM	AA1290/00101	Adipharm EAD

Information from the EMA about the restriction of Fosfomycin antibiotics

The committee for medicinal products for human use (CHMP) finished a review on fosfomycin antibiotics. Fosfomycin antibiotics have been available for many years and, because to their limited use due to fewer potential side effects, they are still active against bacteria which have become resistant to commonly used antibiotics.

Since in recent years the use of fosfomycin has increased, the review aimed to determine the place of fosfomycin in the treatment of infections, considering the latest available evidence. Following conclusions of the review, the EMA is recommending that:

- Fosfomycin given by infusion (drip) into a vein should now only be used when other antibiotic treatments are not suitable or to treat serious infections such as complicated infections of the abdomen, urinary tract or of the skin and soft tissue
- Fosfomycin, for use by mouth, can continue to be used for treating uncomplicated cystitis in women and adolescent girls. Fosfomycin granules (which contain fosfomycin trometamol) can also continue to be used in men undergoing biopsy of the prostate.
- Intramuscular fosfomycin and fosfomycin granules (2 g) given by mouth to children (under 12 years of age) should be suspended as there is no clear evidence that they are sufficiently effective for their currently authorised uses

The CHMP opinion will now be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

In Malta

For Healthcare Professionals

- Fosfomycin for intravenous use

Intravenous fosfomycin should now only be used for the treatment of the following serious infections when other antibiotic treatments are not suitable: complicated urinary tract infections, infective endocarditis, bone and joint infections, hospital-acquired pneumonia including ventilator-associated pneumonia, complicated skin and soft tissue infections, bacterial meningitis, complicated intra-abdominal infections, bacteraemia possibly associated with any of the infections listed above

- Fosfomycin for oral use

The 3 g granules for oral suspension (fosfomycin trometamol) and oral capsules (fosfomycin calcium) can continue to be used for acute, uncomplicated cystitis in women and adolescent girls. Fosfomycin trometamol can also continue to be used prophylactically in men undergoing transrectal prostate biopsy. Fosfomycin is no longer indicated for use for urinary tract infections in children and the paediatric formulation (2 g granules) will therefore be suspended from the market

- Fosfomycin for intramuscular use

As the evidence supporting the use of intramuscular fosfomycin medicines is not sufficient, these products will also be suspended.

The product information for medicines containing fosfomycin will be updated as required to take these recommendations into account.

Information for patients

- Fosfomycin antibiotics given into a vein will now only be used to treat serious infections when other antibiotic treatments are not suitable. These include infections affecting the heart, lungs, blood, brain, abdomen, urinary tract and skin and soft tissue.
- Fosfomycin given as granules dissolved in water and taken by mouth will continue to be used in women and adolescent girls to treat uncomplicated infections of the bladder, and in men who are having a tissue sample taken from their prostate (biopsy).
- Some fosfomycin medicines (medicines given by injection into a muscle and granules for children) will soon no longer be available as there is no evidence that they work well enough.
- If you have any questions about your treatment, speak to your doctor or pharmacist.

For more information please see the European Medicines Agency's [Fosfomycin referral page](#) .

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on fosfomycin antibiotics. Suspected Adverse Drug Reactions (side effects) may be reported using the Medicines Authority Form and sending it to Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000 or online to <http://www.medicinesauthority.gov.mt/adrportal> or to the marketing authorisation holder or their local representatives.

Post-Licensing Directorate Medicines Authority

Healthcare professionals and patients are encouraged to regularly check the Medicines Authority website for product safety updates as these are issued on an ongoing basis.

Feedback Form

The Medicines Authority thanks you for the time taken to read this safety circular. The dissemination of safety circulars is an important process whereby Regulatory Authorities can communicate important issues with respect to the safety of medicines, in order to protect and enhance public health

The Medicines Authority kindly invites your anonymous feedback about the regulatory action being communicated. This may be returned by folding this form (address side up), stapling the ends and then posting (no stamp required)

Feedback:

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Zammit Buildings

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