



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Recommendations to restrict use of fosfomycin antibiotics

EMA has recommended that fosfomycin medicines given by infusion (drip) into a vein should only be used to treat serious infections when other antibiotic treatments are not suitable. Fosfomycin medicines given by mouth can continue to be used to treat uncomplicated bladder infections in women and adolescent girls. They can also be used to prevent infection in men who undergo a procedure whereby a tissue sample is taken from their prostate (biopsy).

EMA further recommends that fosfomycin medicines given by mouth to children (under 12 years of age) and intramuscular formulations (fosfomycin medicines for injection into a muscle) should no longer be used as there are insufficient data available to confirm their benefits to patients.

These recommendations follow a review by EMA's human medicines committee (CHMP) of the safety and effectiveness of these antibiotics.

Fosfomycin-based antibiotics first became available in the 1960s, but their use quickly decreased in favour of other antibiotics with fewer potential side effects. Due in part to their limited use, fosfomycin antibiotics are still active against a number of bacteria that have become resistant to commonly used antibiotics. In recent years, this has led to an increase in the use of fosfomycin in patients with few other treatment options.

The review aimed to determine the place of fosfomycin in the treatment of infections, taking into account the latest available evidence. It concluded that:

- fosfomycin given into a vein should now only be used for treating certain serious infections such as those affecting the heart, lungs, blood and brain or those that are difficult to treat 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. EMA asked companies for further data to justify the continued use of oral medicines containing fosfomycin trometamol and fosfomycin calcium.
- intramuscular fosfomycin and fosfomycin granules for children (2 g) should be suspended as there is no clear evidence that they are sufficiently effective for their currently authorised uses.

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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.

Information for healthcare professionals

EMA has made recommendations for the use of different formulations of fosfomycin:

- 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. In order for fosfomycin calcium preparations to remain authorised, EMA has asked for further information on the benefits and risks to improve the evidence-base behind its use. Fosfomycin trometamol can also continue to be used prophylactically in men undergoing transrectal prostate biopsy. EMA has asked for further information to support dosage recommendation of this indication.

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.

More about the medicine

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) or as 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.

Fosfomycin-containing medicines are available in most EU countries and are marketed under a variety of names: Afastural, Berny Adulti, Danifos Adulti, Fomicyt, Fosfocin, Fosfocina, Fosfocine, Fosfopharm, Fosfuro, Fosmol, Fostrofemge, Gynofostrome, Infectofos, Infeur Adulti, Interfos, Monural, Monuril, Monurol, Rapidnorm, Solufos, Symural, Uridoz, Urifos, Urinex, Urofast, Uromaste and Uroseptic.

More about the procedure

The review of fosfomycin medicines was initiated on 7 December 2018 at the request of Germany, under [Article 31 of Directive 2001/83/EC](#).

The review has been carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which has adopted the Agency's opinion. 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.