14 December 2018
EMA/858775/2018

EMA begins review of medicines containing fosfomycin

EMA has started a review of medicines containing the antibiotic fosfomycin, which is used in a number of EU Member States to treat a range of bacterial infections.

Fosfomycin, an antibiotic that has been in use for many decades, works in a unique way and bacteria resistant to other antibiotics are less likely to be resistant to fosfomycin. There are significant differences between Member States in the authorised uses and doses of fosfomycin medicines. The German medicines authority has requested reappraisal of the role of fosfomycin in the context of increasing resistance to antibiotics. In particular, the indications and dosage of fosfomycin and the adequacy of information on its safety and pharmacological properties will be re-evaluated in the light of up-to-date knowledge on antibacterial therapy.

EMA's human medicines committee (CHMP) will therefore consider the available evidence and make recommendations as to whether the marketing authorisations for fosfomycin-containing medicines should be amended across the EU.

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 or tablets), by infusion (drip) into a vein or by injection into muscle.

When given by mouth it is mainly used for treating adults with urinary tract infections caused by bacteria that are vulnerable to fosfomycin's antibacterial effects. In some EU countries it is also used to prevent infections associated with surgical or diagnostic procedures in the urinary tract.

Fosfomycin infusion is 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 is authorised for treating or preventing various infections including infections of the urinary and reproductive systems.

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Fosfomycin-containing medicines are available in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden and the United Kingdom under a variety of names including 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, Uroseptic.

More about the procedure

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

The review is being carried out by the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt the Agency's opinion. The CHMP opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.