

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للأدوية
والرقابة الدوائية
مسقط

To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES
Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)
Director General of Engineering Affairs, MOH
Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies (MOH)
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No.....77..... dated 31/03/20 regarding European Medicines Agency's recommendations to restrict use of fosfomycin antibiotics.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Medical Device Control, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information

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31 -03-2020



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وَزَارَةُ الصِّحَّةِ
وَالدَّيْوَانَةُ الْعَامَّةُ لِلدَّيْوَانَةِ
وَالرَّقَابَةُ الدَّوْلِيَّةُ
مَسْقُوط

EMA's recommendations to restrict use of fosfomycin antibiotics

The European Medicines Agency 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 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.

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.

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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 is available in Oman.

Healthcare professionals are encouraged to report any adverse events suspected to be associated with the above product or any other medicinal product to the Department of Pharmacovigilance & Drug Information in DGPA&DC.


Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

