Fosfomycin containing medicinal products: the EMA starts a review

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Information on Fosfomycin containing medicinal products

- Fosfomycin is an antibiotic which has been used for many decades in the EU to treat a range of infections, due to its bactericidal activity against wide-spectrum gram-positive and gram-negative bacteria.
- It is given orally (as granules or tablets), by infusion (drip) into a vein or by injection into muscle. When given orally, it is mainly used for treating adults against uncomplicated urinary tract infections caused by bacteria that are vulnerable to Fosfomycin's antibacterial effects
- The authorised doses and uses of Fosfomycin-containing medicinal products are significantly different between the member states

In Malta the following product is authorised:

Active Ingredients	Product Name	Pharmaceutical Form	Classif-cation	Authorisation Number	MAH/license holder
Fosfomycin Trometamol 5.631 gram(s)	Monuril Granules for Oral Solutions 3g	Oral Solution	POM	AA1116/00101	Zambon Spa

Information from the EMA about Fosfomycin

In December 2018 the Committee for Medicinal Products for Human Use (CHMP) started a review on medicinal products containing Fosfomycin at the request of Germany, under Article 31 of Directive 2001/83/EC.

The review was started due to a need re-evaluate the risk-benefit ratio of Fosfomycin across the EU, considering the available evidence. Fosfomycin underwent a revival in recent years due to its bactericidal activity against multidrug resistant (MDR) and extensively drug resistant (XDR) gram positive and gram-negative bacteria. Its unique mechanism of action and chemical structure in addition to the lack of development of new antibiotics active against these pathogens, are related to uncommon cross-resistance and allow for addictive and synergistic effects with other antibiotics.

In the light of up-to-date knowledge on antibacterial therapy, the EMA will evaluate:

- The indications and dosage of Fosfomycin
- The adequacy of information on its safety and pharmacological properties.

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

For more information, visit the European Medicines Agency's Fosfomycin referral page

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Fosfomycin-containing medicinal products. 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 formt (address side up), stapling the ends and then posting (no stamp required)

Feedback:

We thank you for your interest and look forward to hearing your opinion.

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Pharmacovigilance Section

Post-Licensing Directorate

Medicines Authority

Sir Temi Żammit Buildings

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