Review of nasal and mouth sprays containing fusafungine started

15.09.2015 | Circular Number P12/2015

Information on fusafungine (Locabiotal®)

- Fusafungine is an antibacterial and anti-inflammatory medicine used in the form of an aerosol spray or a nasal spray for the treatment of infections of the upper airways such as sinusitis (sinus infection), rhinitis (stuffy and runny nose), rhinopharyngitis (common cold), tonsillitis (inflammation of the tonsils caused by an infection), laryngitis (inflammation of the voice box) and tracheitis (inflammation of the windpipe).
- In Malta, fusafungine is traded under the name Locabiotal® as a prescription-only spray for both intra-nasal and throat application.

Information from the European Medicines Agency about the referral

The European Medicines Agency (EMA) has started a review of these sprays in the EU at the request of the Italian medicines agency (AIFA), following an increase in the rate of reports of serious allergic reactions including anaphylactic reactions with fusafungine.

The majority of the reactions were so-called bronchospastic reactions (excessive and prolonged contractions of the airways' muscles leading to difficulty breathing), which occurred in both adults and children soon after the use of the medicine.

In addition to these safety concerns, AIFA had concerns about the benefit of fusafungine as well as its potential role in promoting antibiotic resistance (the ability of bacteria to grow in the presence of an antibiotic that would normally kill them or limit their growth). It therefore requested a re-evaluation of the benefit-risk balance for fusafungine-containing medicines.

The EMA will now review the available data on the benefits and risks of medicines containing fusafungine, and issue an opinion on the marketing authorisations of these medicines across the European Union (EU).

While the review is ongoing and pending further communication, patients should speak to their doctor or pharmacist if they have any questions or concerns. For more information please visit **www.ema.europa.eu**

In Malta

Information to healthcare professionals

Healthcare professionals are reminded that in Malta Locabiotal is a prescription-only item licensed for use as a local antibacterial adjuvant in the treatment of diseases of the upper respiratory tract.

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The full product information including information on action in case of anaphylaxis can be accessed on http://www.medicinesauthority.gov.mt/home by searching Locabiotal and then clicking on the SPC tabulation.

Reporting Adverse Drug Reactions

Healthcare professionals and patients are encouraged to maintain vigilance on Locabiotal®. Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form or online at **http://www.medicinesauthority.gov.mt/adrportal** or to the marketing authorisation holder or their local representatives.

Prof. John J Borg PhD (Bristol)
Post-licensing Director

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

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