PRAC recommends that fusafungine nose and mouth sprays are no longer marketed

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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 about the PRAC's concerns over serious allergic reactions and limited evidence of benefit

The Pharmacovigilance Risk Assessment Committee (PRAC) at the EMA has recommended that the marketing authorisation for fusafungine-containing medicines be revoked, to the effect that the medicine can no longer be marketed in the EU. This follows a review by the PRAC which concluded that the benefits of fusafungine did not outweigh its risks, particularly the risk of serious allergic reactions

- Serious allergic reactions with fusafungine are rare but can be life-threatening and no measures had been identified to sufficiently reduce this risk.
- The evidence for beneficial effects of fusafungine is weak since fusafungine is used to treat upper airway infections such as rhinopharyngitis (common cold) which are mild and self-limiting in nature.
- Although there is insufficient evidence to show that fusafungine could promote antibiotic resistance this risk could not be excluded and the concern remained.

For these reasons the PRAC has concluded that the benefit-risk balance for fusafungine-containing medicines is negative for all currently authorised uses and has recommended that their marketing authorisation be revoked in the EU.

The PRAC recommendation will now be considered by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position on this issue.

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For Healthcare Professionals and Patients

Further details including advice for patients and healthcare professionals will be published at the time of the CMDh position but in the meantime patients and healthcare professionals should note that the marketing authorisations of fusafungine-containing medicines are not yet revoked and the medicines will remain available while a final decision is pending. Patients who have any questions should speak to their doctor or pharmacist.

For more information on the PRAC's stance on fusafungine please see the press release issued by the European Medicines Agency

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.