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## Fusafungine sprays to be withdrawn due to serious allergic reactions and limited evidence of benefit

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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 CMDh endorsement of the revocation of authorisations for fusafungine sprays used to treat airway infections

The Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) has endorsed the revocation of marketing authorisations for fusafungine sprays in the EU. This follows a review by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) which concluded that the benefits of fusafungine do not outweigh its risks, particularly the risk of serious allergic reactions.

- Fusafungine is an antibiotic and anti-inflammatory nose and mouth spray used to treat upper airway infections such as rhinopharyngitis (common cold).
- Serious allergic reactions including bronchospasm (excessive and prolonged contractions of the airway muscles leading to difficulty breathing) have occurred with these sprays. Although the review found that serious allergic reactions are rare, they can be life-threatening and no measures have been identified to sufficiently reduce or manage this risk.
- The evidence for beneficial effects of fusafungine is weak and considering the mild and self-limiting nature of upper airway infections such as rhinopharyngitis, the benefits of fusafungine were not considered to outweigh the risks.

In addition there were concerns about the potential for fusafungine to promote antibiotic resistance (the ability of bacteria to grow in the presence of an antibiotic that would normally kill

them or limit their growth). Despite the insufficient evidence, the potential risk that fusafungine could increase the risk of antibiotic resistance could not be ruled out.

The benefit-risk balance for fusafungine-containing medicines is therefore negative for all currently authorised uses and following the CMDh consensus position, EU Member States will start revoking the marketing authorisations of these medicines in their territories, according to an agreed timetable.

## **In Malta**

### **Information for patients and healthcare professionals**

- Fusafungine nose and mouth sprays have been used to treat upper airway infections.
- These sprays are being taken off the market in the EU because of rare cases of serious allergic reactions and the lack of strong evidence that these medicines work.
- Upper airway infections are usually mild and self-limiting.
- Healthcare professionals should advise patients on alternative treatments, if needed.
- Patients with any questions should speak to their healthcare professional.

### **National recall of Locabiotol®**

A recall of Locabiotol® 1% Solution for Inhalation (fusafungine), will be performed at pharmacy level by the local representative (Galepharma Ltd on behalf of Les Laboratoires Servier) of this product and will be completed before the Marketing Authorisation (MA066/00801) revocation date i.e. 28th of May 2016, to the effect that no products will remain for sale at pharmacies following the aforementioned revocation date.

### **Reporting Adverse Drug Reactions**

Healthcare professionals and patients are encouraged to maintain vigilance on Locabiotol®. 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.***

The Medicines Authority thanks you for your 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. Your feedback may be returned by folding this page address side up, stapling the ends and then posting (no stamp required)

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