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Fusafungine-containing medicinal products for oromucosal and nasal use will no longer be available on the market

Dear Healthcare professional,

Les Laboratoires Servier, in agreement with the European Medicines Agency and the Malta Medicines Authority, would like to inform you that the marketing authorisation for fusafungine-containing medicinal products for oromucosal and nasal use will be revoked across the EU (Locabiotal, nasal/oromucosal spray). These medicines are used to treat upper airway infections such as rhinopharyngitis.

Summary

- The decision to revoke the marketing authorisations of fusafungine-containing medicinal products is based on concerns over rare but serious cases of hypersensitivity, including allergic reactions and life-threatening anaphylactic reactions, and limited evidence of benefit
- As a consequence fusafungine-containing products will no longer be available
- Patients should be informed that the benefits of these medicines no longer outweigh their risks and they should be advised about alternative therapy.
- The batch recall will be performed at wholesalers and Pharmacies level and will be completed before the Marketing Authorisation revocation date i.e. 28th of May 2016.

Further information on the review of fusafungine

Fusafungine is used as a local antibacterial and anti-inflammatory agent for the treatment of diseases in the upper respiratory airways (sinusitis, rhinitis, rhinopharyngitis, angina, laryngitis, tracheitis).

Concerns over an increased reporting rate of serious hypersensitivity reactions including anaphylactic reactions, in few cases with fatal outcome in connection with fusafungine use led the European Medicines Agency (EMA) to initiate an evaluation of all available data on the efficacy and safety of fusafungine-containing medicines.

The PRAC review found that majority of the serious hypersensitivity reactions occurred soon after the use of the medicine and involved bronchospasm. Although these reactions are rare, they can be life-threatening, and the PRAC considered that no measures had been identified which could sufficiently reduce this risk.

With regard to the benefits, the PRAC considered all available efficacy data, including data which became available since the initial marketing authorisation, and concluded that the evidence for beneficial effects of fusafungine in all approved indications is weak and such effects are not clinically meaningful. In addition, although there is insufficient evidence to conclude on potential risk of inducing bacterial resistance, the risk of cross-resistance cannot be excluded.

Taking into account the mild and self-limited nature of upper airway diseases such as rhinopharyngitis the PRAC considered that the benefits of fusafungine did not outweigh the risks. In addition, use of fusafungine is not supported by any clinical guideline.

On the basis of the currently available data, the EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has concluded that the benefit-risk balance for fusafungine-containing medicines is unfavourable and that the marketing authorisations should be revoked throughout the EU.

National recall

The batch recall which will be performed at wholesalers and pharmacies level, will be completed before the Marketing Authorisation revocation date i.e. 28th of May 2016.

Company contact point

For further inquiries concerning this information, please contact GALEPHARMA Ltd

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