HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Withdrawal of Fusafungine-Containing Medicinal Products

Fusafungine-containing medicinal products (i.e. Locabiotal 1% solution) for oromucosal and nasal use will no longer be available in Ireland and across the EU as the marketing authorisations (i.e. licenses) for these products are being revoked. The European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) recently completed a review of the available data for these products and concluded that the benefits of fusafungine did not outweigh the risks, particularly the risk of serious allergic reactions. The HPRA and Marketing Authorisation Holder (Servier Laboratories) communicated the outcome of this review and the regulatory recommendations in relation to withdrawal of the product in Ireland to healthcare professionals via a Direct Healthcare Professional Communication (DHPC) in April 2016.

The majority of the serious allergic reactions involved bronchospasm and occurred soon after the use of fusafungine. Although the PRAC review found that serious allergic reactions were rare, they may be life-threatening, and no measures were identified that could sufficiently reduce this risk. With regard to the benefits, the PRAC considered that the evidence for the beneficial effects of fusafungine is weak. Therefore, taking into account the mild and self-limiting nature of upper respiratory tract infections such as rhinopharyngitis, the PRAC considered that the benefits of fusafungine did not outweigh the risks.

Advice for Healthcare Professionals

- Fusafungine-containing products will no longer be available on the Irish market.
- Pharmacies and wholesalers have been advised as regards action to take in relation to outstanding stock supplies.
- A Direct Healthcare Professional Communication was circulated to healthcare professionals in April 2016 and is available on the HPRA website (www.hpra.ie).

Key Message

Due to concerns regarding the risk of rare but serious cases of hypersensitivity, including allergic reactions and life threatening anaphylactic reactions, and limited evidence of benefit, the benefit-risk balance for fusafungine-containing medicines is no longer considered favourable and the marketing authorisation for Locabiotal is currently being withdrawn in Ireland.

Further information is available from www.hpra.ie and www.ema.europa.eu

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