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30th June 2015

Locabiotal (fusafungine) nasal/oromucosal spray, solution: new restrictions to minimize the known risk of serious allergic reactions

Dear Healthcare professional,

Les Laboratoires Servier in agreement with the Health Products Regulatory Authority (HPRA) would like to inform you about important changes to the safety information for fusafungine.

Summary
- **Fusafungine is now contraindicated in:**
  - **Children under 12 years** (previously contraindicated in children under 30 months)
  - **Patients with allergic tendencies and bronchospasm** (previously considered as a precaution in use)
- **In case of allergic reaction, fusafungine should be stopped and not readministered.**

Further information on the safety concern and the recommendations

The risk of allergic reactions, although very rare, is already known with fusafungine and a precaution in use for patients with allergic tendencies is included in the product information. Following an increased incidence in the reporting of allergic reactions, Les Laboratoires Servier performed an analysis of the case reports to further characterise the risk and define appropriate risk minimisation measures. This led to subsequent review by the HPRA.

The analysis and review of serious cases of allergic reactions revealed that the majority of these reactions consisted of bronchospastic reactions, angioedema and related reactions and anaphylactic reaction/shock. Furthermore, among patients in whom the information was available, bronchospastic reactions occurred more frequently in patients with a medical history of allergies than in those without an allergic background.

An analysis of paediatric cases of allergic reactions was also conducted. This revealed that the majority of paediatric reports of allergic reactions associated with fusafungine were reported in children less than 12 years and 42% (16/38) were assessed as serious, including one case with a fatal outcome.

As a result of this analysis and review, the previously known very rare risk of allergic reactions was confirmed and new restrictions were introduced with the aim of reducing exposure to the medicine in the most vulnerable groups.

Further information

Locabiotal nasal/oromucosal spray solution is indicated for the treatment of local infections of the nasal passages and oropharynx due to micro-organisms sensitive to this anti-infective.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions in accordance with the HPRA spontaneous reporting system. Suspected adverse reactions should be reported to the HPRA using a Yellow Card obtained either from the HPRA, or electronically via the website at www.hpra.ie. Adverse reactions can also be reported to the HPRA by calling (01) 676 4971.

Company contact point

For further inquiries concerning this information, please contact the Medical Information Department of SERVIER Laboratories Ireland.Block 2, West Pier Business Campus, Old Dunleary Road, Dun Laoghaire, Co. Dublin.
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Yours sincerely

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