

## Direct Healthcare Professional Communication

### **Locabiotol (fusafungine) nasal/oromucosal spray, solution New contra-indications and recommendations to minimize the risk of serious allergic reactions**

Dear Healthcare professional,

Les Laboratoires Servier with the Medicines Authority would like to inform you about new recommendations on the use of fusafungine, nasal/oromucosal spray, solution.

#### **Summary**

- Fusafungine is now contra-indicated in:
  - *Children under 12 years* (fusafungine was previously contra-indicated in children under 30 months)
  - *Patients with allergic tendencies and bronchospasm* (previously considered as a precaution for use)

#### **Further information**

Les Laboratoires Servier performed recently a periodic review of post-marketing cases of "Allergic reactions" (respiratory and skin disorders).

- Taking account the observation of further rare but severe cases of allergic reactions reported in the pediatric population less than 12 year-old, Les Laboratoires Servier has proposed to contra-indicate the use of fusafungine in children under 12 years.
- Besides, this analysis showed that serious allergic reactions are more frequently observed in patients with an allergic background than in patients without medical history of allergies. Therefore, Les Laboratoires Servier has proposed to strengthen the precaution for use in patients with allergic tendencies and bronchospasm and to contra-indicate the use of fusafungine in these patients.

#### **Call for reporting**

Please report any suspected adverse reactions to the Medicines Authority Post-licensing Directorate by filling in an ADR form and sending by post to 203, Level 3, Rue D'Argens, Gzira GZR 1368, MALTA, or by email to [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt) or submitting online at [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal).

**Company contact point**

For further inquiries concerning this information, please contact GALEPHARMA Ltd  
Tel: +(356) 21 247 082 – 14-15, Strait Street, Valetta, VLT1430, Malta.

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