

## Direct Healthcare Professional Communication

### Bioparox(fusafungine) spray: new contra-indications and recommendations to minimize the risk of serious allergic reactions

Dear Healthcare professional,

Les Laboratoires Servier would like to inform you about new recommendations on the use of fusafungine spray.

#### 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

As a reminder, there is a need to report any suspected adverse reactions in accordance with the national spontaneous reporting system Scientific Center of Drug and Medical Technology Expertise after academician Emil Gabrielyan:

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**Company contact point**

For further inquiries concerning this information, please contact the Armenia Representative Office of Les Laboratoires Servier, Local Responsible person for Pharmacovigilance Mariam Antonyan, tel: +374 91 03 20 80, +374 10 50 50 74, e-mail: [mariam.antonyan@servier.com](mailto:mariam.antonyan@servier.com), postal address: 1 Hyusisain Ave., «NORD» Business Centre, 5th floor, office N13, 0001 Yerevan, Armenia.