



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2015
EMA/323030/2015
Procedure Management and Committees Support

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, marketing authorisation holders in the member states for for fusafungine containing medicinal products for oromucosal and nasal use

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1420

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Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	Servier Austria GmbH	Locabiosol	Fusafungine 50mg/5 MI	Nasal/Oromucosal Spray, Solution
Belgium	Servier Benelux N.V.-S.A.	Locabiotol	Fusafungine 50mg/5 MI	Nasal/Oromucosal Spray, Solution
Bulgaria	Les Laboratoires Servier (Suresnes)	биопарокс	Fusafungine 50mg/10 MI	Nasal/Oromucosal Spray, Solution
Cyprus	Les Laboratoires Servier (Suresnes)	Locabiotol	Fusafungine 500mg/100 MI	Nasal/Oromucosal Spray, Solution
Cyprus	Les Laboratoires Servier (Suresnes)	Locabiotol Lp	Fusafungine 1g/100 MI	Nasal/Oromucosal Spray, Solution
Czech Republic	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 0.5g/100ml	Nasal/Oromucosal Spray, Solution
Estonia	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 5mg/MI	Nasal/Oromucosal Spray, Solution
Germany	Les Laboratoires Servier (Suresnes)	Locabiosol	Fusafungine 0.125mg Spray	Nasal/Oromucosal Spray, Solution
Germany	Les Laboratoires Servier (Suresnes)	Locabiosol	Fusafungine 0.5mg Spray	Nasal/Oromucosal Spray, Solution
Greece	Servier Hellas	Locabiotol	Fusafungine 1g/100ml	Nasal/Oromucosal Spray, Solution
Greece	Servier Hellas	Locabiotol	Fusafungine 500mg/100 MI	Nasal/Oromucosal Spray, Solution
Hungary	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 50mg/10 MI	Nasal/Oromucosal Spray, Solution
Hungary	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 50mg/10 MI	Nasal/Oromucosal Spray, Solution
Ireland	Servier Laboratories Ireland Ltd	Locabiotol	Fusafungine 1g/100ml	Nasal/Oromucosal Spray, Solution
Italy	Les Laboratoires Servier (Suresnes)	Locabiotol	Fusafungine 1g/100 MI	Nasal/Oromucosal Spray, Solution
Latvia	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine, 0.125 Mg/Dose	Nasal/Oromucosal Spray, Solution

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Latvia	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 0.5g/100 MI	Nasal/Oromucosal Spray, Solution
Lithuania	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 50mg/10 MI	Nasal/Oromucosal Spray, Solution
Luxembourg	Servier R&d Benelux N.V. -S.A.	Locabiotol 1%	Fusafungine 1g/100ml	Nasal/Oromucosal Spray, Solution
Malta	Les Laboratoires Servier (Suresnes)	Locabiotol	Fusafungine 50mg/5 MI	Nasal/Oromucosal Spray, Solution
Portugal	Servier Portugal, Especialidades Farmacêuticas, Lda.	Locabiosol	Fusafungine 0.5g/100 MI	Nasal/Oromucosal Spray, Solution
Romania	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 50mg/10 MI	Nasal/Oromucosal Spray, Solution
Slovakia	Les Laboratoires Servier (Suresnes)	Bioparox	Fusafungine 0.5g/100 MI	Nasal/Oromucosal Spray, Solution
Spain	Danval, S.A.	Fusaloyos	Fusafungine 1g/100ml	Nasal/Oromucosal Spray, Solution