



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 September 2015
EMA/593548/2015

Start of review of nasal and mouth sprays containing fusafungine

The European Medicines Agency (EMA) has started a review of nasal and mouth sprays containing the antibiotic fusafungine, used to treat infections of the upper airways such as sinusitis (sinus infection) and tonsillitis (inflammation of the tonsils caused by an infection).

The review has been requested by the Italian medicines agency (AIFA) following an increase in the rate of reports of serious allergic reactions including anaphylactic reactions with fusafungine. The majority of the serious allergic reactions were so-called bronchospastic reactions (excessive and prolonged contractions of the airways' muscles leading to difficulty breathing), which occurred in both adults and children soon after the use of the medicine.

In addition to these safety concerns, AIFA had concerns about the benefit of fusafungine as well as its potential role in promoting antibiotic resistance (the ability of bacteria to grow in the presence of an antibiotic that would normally kill them or limit their growth). It therefore requested a re-evaluation of the benefit-risk balance for fusafungine-containing medicines.

The EMA will now review the available data on the benefits and risks of medicines containing fusafungine, and issue an opinion on the marketing authorisations of these medicines across the European Union (EU).

While the review is ongoing and pending further communication, patients should speak to their doctor or pharmacist if they have any questions or concerns.

More about the medicine

Fusafungine is an antibacterial and anti-inflammatory medicine used in the form of an aerosol spray or a nasal spray for the treatment of the following infections of the upper airways: sinusitis (sinus infection), rhinitis (stuffy and runny nose), rhinopharyngitis (common cold), tonsillitis (inflammation of the tonsils caused by an infection), laryngitis (inflammation of the voice box) and tracheitis (inflammation of the windpipe).



Fusafungine-containing medicines have been authorised in the EU through national approval procedures. They are currently marketed under various trade names (Bioparox, Fusaloyos, Locabiotol and Locabiosol) in the following countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, Slovakia and Spain.

More about the procedure

The review of fusafungine-containing medicines has been initiated at the request of the Italian medicines agency (AIFA), under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. As fusafungine-containing medicines are all authorised nationally, the PRAC recommendations will be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. The CMDh is a body representing EU Member States as well as Iceland, Liechtenstein and Norway. It is responsible for ensuring harmonised safety standards for medicines authorised via national procedures across the EU.