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PRAC recommends that fusafungine nose and mouth sprays are no longer marketed

Committee had concerns over serious allergic reactions and limited evidence of benefit

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that the marketing authorisation for fusafungine-containing medicines be revoked, so the medicines can no longer be marketed in the EU. This follows a review by the PRAC which concluded that the benefits of fusafungine did not outweigh its risks, particularly the risk of serious allergic reactions. Fusafungine is an antibiotic and anti-inflammatory nose and mouth spray used to treat upper airway infections such as rhinopharyngitis (common cold).

The majority of the serious allergic reactions occurred soon after the use of the medicine and involved bronchospasm (excessive and prolonged contractions of the airway muscles leading to difficulty breathing). Although the PRAC review found that serious allergic reactions are rare, they can be life-threatening, and the PRAC considered that no measures had been identified to sufficiently reduce this risk.

With regard to the benefits, the PRAC considered that the evidence for beneficial effects of fusafungine is weak. Taking into account the mild and self-limited nature of upper airway diseases such as rhinopharyngitis the PRAC considered that the benefits of fusafungine did not outweigh the risks.

In addition, the PRAC was concerned about the potential for fusafungine to promote antibiotic resistance (the ability of bacteria to grow in the presence of an antibiotic that would normally kill them or limit their growth). Although the evidence was insufficient to conclude on the risk of resistance, this risk could not be excluded.

The PRAC therefore concluded that the benefit-risk balance for fusafungine-containing medicines is negative for all currently authorised uses and recommended that their marketing authorisation be revoked in the EU.

The PRAC recommendation will be considered by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position. Further details including advice for patients and healthcare professionals will be published at the time of the CMDh position.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Patients and healthcare professionals should note that the marketing authorisations of fusafungine-containing medicines are not yet revoked and the medicines will remain available while a final decision is pending. Further information will be issued in due course. Patients who have any questions should speak to their doctor or pharmacist.

More about the medicine

Fusafungine is an antibiotic and anti-inflammatory medicine used in the form of a nasal and oromucosal (to be applied to the mouth) 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) and laryngitis (inflammation of the voice box).

Fusafungine-containing medicines have been available in a number of EU countries for over 50 years. They have been authorised through national approval procedures. They are currently marketed under various trade names (Bioparox, Fusaloyos, Locabiotal and Locabiosol) in the following countries: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, Slovakia and Spain.

More about the procedure

The review of fusafungine-containing medicines was initiated on 11 September 2015 at the request of Italy, under Article 31 of Directive 2001/83/EC.

The review has been carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which has made a set of recommendations. During its review the PRAC consulted EMA's paediatric scientific committee as well as experts in the field of anti-infective medicines. The marketing authorisation holders may request a re-examination within 15 days of being notified of the PRAC recommendation.

As fusafungine-containing medicines are all authorised nationally, the PRAC recommendation 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 regulatory 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.

If the CMDh position is agreed by consensus, the agreement will be implemented directly by the Member States where the medicines are authorised. Should the CMDh position be adopted by majority vote, the CMDh position will be sent to the European Commission for an EU-wide legally binding decision.

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu