1 April 2016
EMA/227560/2016

CMDh endorses revocation of authorisations for fusafungine sprays used to treat airway infections

Medicines to be withdrawn due to serious allergic reactions and limited evidence of benefit

The CMDh[1] has endorsed by consensus the revocation of marketing authorisations for fusafungine sprays in the EU. This follows a review by EMA's Pharmacovigilance Risk Assessment Committee (PRAC) which concluded that the benefits of fusafungine do 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).

Serious allergic reactions have occurred soon after the use of these sprays and involved bronchospasm (excessive and prolonged contractions of the airway muscles leading to difficulty breathing). Although the review found that serious allergic reactions are rare, they can be life-threatening and no measures have been identified to sufficiently reduce or manage this risk.

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

In addition, there were concerns 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 there is insufficient evidence to establish that fusafungine can increase the risk of resistance, this risk could not be ruled out. The benefit-risk balance for fusafungine-containing medicines is therefore negative for all currently authorised uses.

Following the CMDh consensus position, EU Member States will start revoking the marketing authorisations of these medicines in their territories, according to an agreed timetable.

Information for patients and healthcare professionals

- Fusafungine nose and mouth sprays have been used to treat upper airway infections.
- These sprays are being taken off the market in the EU because of rare cases of serious allergic reactions and the lack of strong evidence that these medicines work.

[1] The CMDh is a medicines regulatory body representing the European Union (EU) Member States

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- Upper airway infections are usually mild and self-limiting.
- Healthcare professionals should advise patients on alternative treatments, if needed.
- Patients with any questions should speak to their healthcare professional.

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 several EU countries for over 50 years. They were authorised through national approval procedures under various trade names (Bioparox, Fusaloyos, Locabiotal 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.

In some Member States, these medicines were available without prescription.

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 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.

As fusafungine-containing medicines are all authorised nationally, the PRAC recommendations were forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which adopted a final position on 31 March 2016.

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.

As the CMDh adopted its position by consensus, the measures recommended by the PRAC will be implemented directly by the Member States where the medicines are authorised, according to an agreed timetable.

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