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PRAC starts safety review of pseudoephedrine-containing medicines

EMA's safety committee (PRAC) has started a review of medicines containing pseudoephedrine following concerns about the risk of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), conditions affecting blood vessels in the brain. Pseudoephedrine is taken by mouth and is used alone or in combination with other medicines to treat nasal congestion (a blocked nose) resulting from a cold, flu or allergy.

PRES and RCVS can involve reduced blood supply (ischaemia) to the brain and may cause major and life-threatening complications in some cases. Common symptoms associated with PRES and RCVS include headache, nausea and seizures.

The review follows new data from a small number of cases of PRES and RCVS in people using pseudoephedrine-containing medicines which were reported in pharmacovigilance databases and the medical literature.

Pseudoephedrine-containing medicines have a known risk of cardiovascular and cerebrovascular ischaemic events (side effects involving ischaemia in the heart and brain), including stroke and heart attack. Restrictions and warnings are already included in the medicines' product information to reduce these risks.

Considering the seriousness of PRES and RCVS, the overall safety profile of pseudoephedrine and the indications for which the medicines are approved, the PRAC will review available evidence and decide whether the marketing authorisations for pseudoephedrine-containing medicines should be maintained, varied, suspended or withdrawn across the EU.

More about the medicine

Pseudoephedrine works by stimulating nerve endings to release the chemical noradrenaline, which causes the blood vessels to constrict (narrow). This reduces the amount of fluid released from the vessels, resulting in less swelling and less mucus production in the nose.

Pseudoephedrine-containing medicines are authorised in various EU Member States alone, or in combination with medicines to treat symptoms of a cold and flu such as headache, fever and pain, or allergic rhinitis (inflammation of the nasal passages) in people with nasal congestion.

Within the EU, pseudoephedrine-containing medicines are available under various trade names, including Actifed, Aerinaze, Aspirin Complex, Clarinase, Humex rhume, and Nurofen Cold and Flu.

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More about the procedure

The review of medicines containing pseudoephedrine has been initiated at the request of the French medicines agency (ANSM) 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. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt an opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.