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Review of almitrine-containing medicines started

The European Medicines Agency has started a review of almitrine–containing medicines when taken by mouth for chronic respiratory diseases. Chronic respiratory diseases are long-term diseases of the airways and lungs such as chronic obstructive pulmonary disease (COPD), a condition in which the airways and air sacs in the lungs become damaged or blocked.

Almitrine has been authorised in some EU Member States since 1982 for chronic respiratory failure (inability of the lungs to take in oxygen and get rid of carbon dioxide properly) with hypoxaemia (lower than normal levels of oxygen in the blood), which can be serious and life threatening in patients with COPD. However, there are concerns that almitrine treatment may lead to side effects including marked weight loss and peripheral neuropathy (nerve damage in the hands and feet) in some patients. In addition, the evidence does not seem to support the effectiveness of almitrine as part of current management of COPD.

The European Medicines Agency will review all available data on safety and effectiveness to determine the benefit-risk balance of almitrine-containing medicines when these medicines are taken by mouth for chronic respiratory diseases.

More about the medicine

Almitrine is a respiratory stimulant, a medicine that stimulates the part of the brain responsible for the breathing reflex. In the EU, it is available in France, Poland and Portugal as tablets containing 50 mg of almitrine (Vectarion, Armanor).

More about the procedure

The review has been initiated at the request of the French medicines agency 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 almitrine-containing medicines are all authorised nationally, the PRAC recommendation will be forwarded to the Co-

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which is a regulatory body that represents national medicines regulatory authorities of the EU Member States. This will result in harmonised measures to be implemented in all Member States.