



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends suspension of all buflomedil-containing medicines

Benefits of vasoactive agents do not outweigh risks of serious cardiological and neurological side effects

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) concluded a review of the safety and efficacy of buflomedil, saying that the risks of these medicines, particularly the risks of severe cardiological and neurological adverse reactions, are greater than their limited benefits in the treatment of patients with chronic peripheral arterial occlusive disease (PAOD). The Committee therefore recommended that the marketing authorisations of all buflomedil-containing medicines be suspended in all European Union (EU) Member States where they are currently authorised.

Doctors should stop using buflomedil and consider alternative treatment options, including managing underlying health problems which can increase the risk of PAOD, such as diabetes, high blood pressure and smoking.

Patients using buflomedil-containing medicines should make an appointment with their doctor at a convenient time to discuss their ongoing treatment.

Buflomedil, a vasoactive agent, is used to treat the symptoms of PAOD. This is a condition where the body's large arteries become obstructed, causing symptoms such as pain and weakness, particularly in the legs. Buflomedil is used in patients with stage II PAOD, who experience severe pain when walking even relatively short distances.

The review of buflomedil was initiated following the suspension of the marketing authorisation in France by the French regulatory authority in February 2011.

The CHMP considered all available data on the benefits and risks of buflomedil, including the benefit-risk assessment carried out by France, data from clinical studies, post-marketing surveillance and published literature, as well as from poison control centres in the EU.



Following review of these data the Committee concluded that:

- there was a risk of serious neurological and cardiac side effects in patients taking buflomedil under normal conditions of use and that risk minimisation measures such as changes to the packaging of the medicine, recommendations on adjusting the dose for patients with kidney problems and restrictions on the medicines' use in certain patients had not been able to reduce these risks to an acceptable level;
- due to the narrow therapeutic index (i.e. the small difference between buflomedil's therapeutic dose and its toxic dose) there was a significant risk of adverse events, particularly in elderly patients and in patients with certain conditions such as kidney problems, which are common in PAOD;
- data in support of the benefit of the medicine for patients were limited and of poor quality.

The Committee was therefore of the opinion that the benefits of buflomedil-containing medicines no longer outweigh their risks, and recommended that marketing of these medicines should be suspended throughout the EU.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Buflomedil-containing medicines have been authorised in the EU since the 1970s via national procedures. Buflomedil is authorised in the form of tablets, an oral solution or a solution for injection in Austria, Belgium, Cyprus, France, Germany, Greece, Italy, Luxembourg, the Netherlands, Poland, Portugal and Spain under the invented name Loftyl and other trade names.
3. The review was carried out under Article 107 of Directive 2001/83/EC. This type of procedure is triggered when a Member State varies, suspends or revokes the marketing authorisation for a medicine in its territory because of a safety issue.
4. The CHMP's recommendation will be sent to the European Commission for the adoption of a decision.
5. All other opinions and documents adopted by the CHMP at their November 2011 plenary meeting will be published on Friday, 18 November 2011 at 12.00 noon UK time on a dedicated web page.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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