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Press Office

Press release

European Medicines Agency recommends suspension of oral buflomedil-containing medicines

Oral presentations of vasoactive agent should no longer be prescribed in the European Union; review of injectable buflomedil continues

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) recommended that the supply of oral buflomedil-containing medicines be suspended in all European Union (EU) Member States where it is currently authorised. This is an interim recommendation pending the finalisation of the continuing review of the benefits and risks of buflomedil solution for injection. The CHMP will adopt an opinion at the end of the full review.

Buflomedil, a vasoactive agent, is used to treat the symptoms of peripheral arterial occlusive disease (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 decision of the French regulatory authority in February 2011 to suspend the marketing authorisation. The decision was taken because serious and sometimes fatal neurological and cardiac side effects, mainly related to accidental or intentional overdose, continued to occur, despite measures put in place by regulatory authorities previously to reduce the risk of overdosing.

The CHMP considered all available data on the benefits and risks of oral 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.

The Committee concluded that measures put in place by regulatory authorities had not been able to prevent serious side effects, especially related to overdose, from occurring. The CHMP also noted that the medicine had only been shown to have a limited benefit for patients, measured in terms of walking distance, and the studies assessed had a number of weaknesses. The Committee was therefore of the opinion that the benefits of buflomedil-containing medicines in the form of tablets or an oral solution

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do not outweigh their risks, and recommended that the supply of these medicines should be suspended throughout the EU.

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

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

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 available in the form of tablets or an oral solution 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. It informs the CHMP so that a EU-wide decision can be reached .
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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