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Press Office

Press release

European Medicines Agency recommends revocation of marketing authorisations for bufexamac

Medicines to be taken off EU markets because of high risk of contact allergies

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended that marketing authorisations for bufexamac-containing medicines be revoked.

The CHMP recommendations follow a scientific review, which identified a high risk of sometimes serious contact allergic reactions with bufexamac. The risk was even higher in patients with pre-disposing conditions, such as certain forms of eczema, for which bufexamac is frequently prescribed. Furthermore, the allergic reactions caused by bufexamac are very similar to the disease being treated, which may lead to a potential delay in the correct diagnosis and treatment of patients. It is also likely that the difficulty to differentiate between a treatment failure and an allergic reaction has led to the cases of contact allergic reaction being underreported.

In addition to this, the data to support the effectiveness of bufexamac are very limited, so the Committee concluded that, based on the available information, the benefits of the bufexamac-containing medicines did not outweigh its risks and recommended that they be taken off the market across the European Union.

Bufexamac is a non-steroidal anti-inflammatory drug (NSAID), used as topical formulations to treat dermatological diseases (eczema and dermatitis) and proctological conditions (haemorrhoids and anal fissure). Bufexamac-containing medicines have been available in EU Member States since the 1970s.

It had been known for some time that bufexamac may trigger contact allergic reactions. This has led to restrictions on the use of the medicines in a number of EU countries over the years. The latest review of the benefits and risks of bufexamac was completed in December 2009 by the German medicines regulatory authority, which decided to withdraw all marketing authorisations for bufexamac in Germany. As required by EU legislation, the German authority informed the CHMP of its regulatory action, so that the Committee could prepare an opinion on whether the marketing authorisations for these medicines should be revoked all over the EU or whether they should be maintained, changed or suspended.

Based on the available data the CHMP concluded that the marketing authorisations for Bufexamac should be revoked.

The CHMP's opinion has now been sent to the European Commission for the adoption of a decision.

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Notes

1. More information on bufexamac is available in a question and answer document.
2. Medicines containing bufexamac have been authorised as Parfenac, Bufal, Calmaderm, Fansamac, Mastu S, Parfenoide, Proctosan or other trade names in Austria, Bulgaria, the Czech Republic, France, Hungary, Italy, Latvia, Lithuania, Luxembourg, Portugal, Romania and Slovakia. They may be available as creams, rectal ointments and suppositories. Because of the restrictions placed on these medicines over the years, their use in the EU is limited.
3. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.ema.europa.eu

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