21 January 2010
EMA/39408/2010
Press Office

Press release

European Medicines Agency recommends suspension of marketing authorisations for sibutramine

Weight-loss medicine associated with increased risk of cardiovascular events to be removed from all markets in the European Union

The European Medicines Agency has finalised a safety review of medicines containing sibutramine. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the risks of these medicines are greater than their benefits and recommended the suspension of marketing authorisations for these medicines across the European Union.

Sibutramine-containing medicines are authorised as Reductil, Reduxade and Zelium and other tradenames in the European Union. They are used to promote weight-loss in obese patients and in overweight patients who also have other risk factors such as type-2 diabetes or dyslipidaemia (abnormal levels of fat in the blood), together with diet and exercise.

Doctors should no longer prescribe, and pharmacists should no longer dispense the medicine. Patients currently taking sibutramine should make an appointment with their doctor at the next convenient time to discuss alternative measures to lose weight. Patients who wish to stop treatment before seeing their doctor can do so at any time.

The review was initiated because data from the Sibutramine Cardiovascular Outcome Trial (SCOUT) showed an increased risk of serious, non-fatal cardiovascular events, such as stroke or heart attack, with sibutramine compared with placebo. The SCOUT trial, in which nearly 10,000 patients were enrolled for up to six years, was designed to determine the impact of weight loss with sibutramine on cardiovascular problems in a large group of overweight and obese subjects with known or high risk for cardiovascular disease.

The CHMP noted that the use of sibutramine was not in accordance with the prescribing information for most of the patients enrolled in the SCOUT study, as sibutramine is contra-indicated in patients with known cardiovascular disease. The treatment duration in the study was also longer than normally recommended. However, because obese and overweight patients are likely to have a higher risk of cardiovascular events, the Committee was of the opinion that the data from SCOUT are relevant for the use of the medicine in clinical practice.

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The Committee also noted that the data from available studies show that the weight loss achieved with sibutramine is modest and may not be maintained after stopping. The CHMP was therefore of the opinion that the benefit of sibutramine as a weight-loss aid do not outweigh the cardiovascular risks.

The Committee's recommendation for the suspension of the marketing authorisations has now been forwarded to the European Commission for the adoption of a decision.

Notes

1. More information is available in a question-and-answer document.
2. Sibutramine is authorised at the level of the European Union Member States under the tradenames Afibon, Ectiva, Lindaxa, Meissa, Meridia, Minimacin, Minimectil, Obesan, Sibutral, Sibutril, Siluton, Sitrane, Redoxade, Reductil, Zelixa and Zelium.
3. The review was initiated under Article 107 of the Community code relating to medicinal products for human use (Directive 2001/83/EC). This type of procedure is initiated in cases where a Member State withdraws, suspends or changes the marketing authorisation of a decentralised authorised medicine as a result of the evaluation of safety data. It provides for a harmonised European approach because the CHMP is asked to prepare an opinion on whether or not the regulatory actions should be implemented throughout the European Union.
4. The suspension of a marketing authorisation is a precautionary measure, during which time a medicinal product is unavailable. The lifting of the suspension is conditional on the marketing authorisation holder resolving the issues identified by the Agency and the subsequent decision of the European Commission.
5. A press release with an update on the ongoing review was issued following the December 2009 CHMP meeting: http://www.ema.europa.eu/pdfs/general/direct/pr/81787609en.pdf
6. 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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