



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency updates on ongoing safety review of sibutramine

Weight-loss medicine assessed over cardiovascular concerns

The European Medicines Agency is reviewing data that indicate an increased risk of serious cardiovascular events, such as stroke or heart attack, with medicines containing sibutramine.

Sibutramine containing medicines (authorised as Reductil, Reduxade and Zelium and other tradenames) are indicated for use 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).

The data come from the Sibutramine Cardiovascular OUTcomes (SCOUT) trial, which included nearly 10,000 patients enrolled for up to six years. This study set out to determine how long-term treatment with sibutramine would impact on the risk of developing cardiovascular events in a large group of overweight and obese patients with known or high risk of cardiovascular disease. These high-risk patients were actively selected for the study even though treatment with sibutramine would have been contraindicated in the majority of cases.

Because of the seriousness of the findings of the SCOUT study, the Agency's Committee for Medicinal Products for Human Use (CHMP) is currently assessing the implications of these findings for the use of sibutramine in normal clinical practice.

In the meantime, doctors and patients are reminded to use sibutramine-containing medicines with caution, and only in accordance with the currently approved product information. In particular, these medicines should not be used in patients with coronary artery disease, congestive heart failure, peripheral arterial occlusive disease, arrhythmia and cerebrovascular disease (stroke or transient ischemic attack).

All patients should be regularly monitored for increases in blood pressure and heart rate. Patients who do not lose at least 5% of their body weight within 3 months should stop treatment. The maximum treatment duration should not exceed one year.

The Committee will conclude its review at its January 2010 meeting. Further information will be provided about the outcome at that stage.



Notes

1. Sibutramine-containing medicines have been authorised in the European Union (EU) since 1999. They are available in the European Union under the following names: Afibon, Ectiva, Lindaxa, Meissa, Meridia, Minimacin, Minimectil, Obesan, Reductil, Reduxade, Sibutral, Sibutril, Siluton, Sitrane, Zelium and Zelixa.
2. 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 considers the need for a regulatory action (withdrawal, suspension or changes to 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.
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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