Sibutramine: Suspension of marketing authorisation as risks outweigh benefits

The European Medicines Agency (EMA) has completed a review of the obesity medicine sibutramine (Reductil) on the basis of new safety information from a large clinical trial, the Sibutramine Cardiovascular OUTcomes (SCOUT) study. The review has found that the cardiovascular risks of sibutramine outweigh its benefits. The EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended suspension of the marketing authorisation for this medicine across the European Union.

Further information is available on the EMA website.

Advice for healthcare professionals and patients

- Doctors should not issue any new prescriptions for sibutramine and should review the treatment of those who are currently taking this medicine.
- Pharmacists should not dispense any prescriptions for sibutramine and should advise patients to make an appointment to see their doctor at the next convenient time.
- Patients who are currently being treated with sibutramine should be advised to schedule an appointment at the next convenient time with their doctor to discuss alternative measures to lose weight, including use of diet and exercise regimes. Patients may stop treatment before their appointment if they wish.

A Direct Healthcare Professional Communication and a series of questions and answers is available for download below.

Direct Healthcare Professional Communication
Questions and answers

Page last modified: 21 January 2010