22 July 2010
EMA/459173/2010
Press Office

Press release

European Medicines Agency recommends restricting the use of modafinil

Doctors and patients advised to use modafinil for treatment of narcolepsy only; all other indications to be removed from product information

The European Medicines Agency has recommended restricting the use of modafinil-containing medicines. The medicine should only be used to treat sleepiness associated with narcolepsy. Doctors and patients should no longer use the medicine for the treatment of idiopathic hypersomnia, excessive sleepiness associated with obstructive sleep apnoea and chronic shift work sleep disorder.

Modafinil is a wakefulness promoting agent, currently licensed in 21 countries in Europe. They are available under the following invented names: Modasomil, Modiodal, Provigil and Vigil, and as generic medicines.

The review by the Agency's Committee for Medicinal Products for Human Use (CHMP) was initiated because of a number of safety concerns, relating to psychiatric disorders, skin and subcutaneous tissue reactions as well as significant off-label use and potential for abuse.

On the basis of the available data the Committee concluded that the benefits of these medicines only outweighed their risks in the therapeutic indication narcolepsy, a chronic sleep disorder characterised by excessive daytime sleepiness. For all other indications the Committee found that the risk for development of skin or hypersensitivity reactions and neuropsychiatric disorders outweighed the evidence for clinically important efficacy. Therefore, the Committee concluded that all other indications should be withdrawn from the marketing authorisations of these medicines.

The risk of development of serious skin and hypersensitivity adverse reactions appears to be higher in children than in adults. The Committee concluded that the product information should carry a recommendation saying that modafinil should not be prescribed to children.

The CHMP also identified particular cardiovascular risks with modafinil and recommended that the use of the medicine be contraindicated in patients with uncontrolled moderate to severe hypertension and in patients with cardiac arrhythmias.

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There are some reports that modafinil is being used recreationally for 'performance enhancement'. However, the data seen by the Committee did not allow it to make firm recommendations regarding this risk. The CHMP has requested that the marketing authorisation holders continue to provide further information to monitor the potential for abuse.

The CHMP's recommendations have been forwarded to the European Commission for the adoption of a binding decision.

Notes

1. More information about modafinil is available in the Questions and answers on the review of medicines containing modafinil.
2. The review of modafinil was initiated under Article 31 of Directive 2001/83/EC, as amended. This type of procedure may be initiated in specific cases where the interest of the Community is involved. The expression 'Community interest' has a broad meaning but it refers particularly to the interests of the public health in the Community, for example following concerns related to the quality, efficacy and/or safety of a medicinal product or new pharmacovigilance information.
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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