IRISH MEDICINES BOARD

Acomplia (rimonabant)

The Irish Medicines Board (IMB) suspended the marketing and use of Acomplia in Ireland on 23rd October 2008 following a recommendation issued by the European Medicines Agency (EMEA) on the same date. This national action was taken following review of the product by the EMEA's Committee for Medicinal Products for Human Use (CHMP) who concluded that the benefits of Acomplia no longer outweigh its risks and that the marketing authorisation should be suspended across the European Union (EU).

Acomplia (rimonabant) is a selective cannabinoid-1 receptor antagonist that reduces the appetite and was authorised in the EU in June 2006 'as an adjunct to diet and exercise for the treatment of obese patients (BMI ≥ 30kg/m^2), or overweight patients (BMI> 27kg/m^2) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia'. Warnings about psychiatric side effects, in particular depression, were included in the product information since the product was first authorised and these warnings were continuously updated and strengthened to include further contraindications and more detailed information on these concerns, in order to manage the risks associated with use of Acomplia.

Following assessment of the available information on the benefits and risks of Acomplia, including data from studies completed since it was granted marketing authorisation, the CHMP confirmed that there is an approximate doubling of the risk of psychiatric disorders in obese or overweight patients taking Acomplia compared to those taking placebo.

The CHMP considered that the new data from post-marketing experience and ongoing clinical trials indicated that serious psychiatric disorders may occur more commonly than suggested by the initial assessment of Acomplia. The CHMP was also of the opinion that these psychiatric side effects could not be adequately addressed by further risk minimisation measures.

In addition, the CHMP noted that the effectiveness of Acomplia in clinical practice is more limited than was expected on the basis of the clinical trials, because available data indicate that patients generally take Acomplia only for a short period.

Information regarding the suspension and use of Acomplia in Ireland was distributed by letter/fax/email networks to healthcare professionals, with information also highlighted on the IMB and professional body websites, advising of the action taken and requesting that no further prescriptions for Acomplia should be written or dispensed. In addition, a recall of the product was undertaken to patient level and patients were advised via media statements that they should discontinue treatment with Acomplia and should consult their doctor or pharmacist at a convenient time to discuss treatment options.

Healthcare professionals are reminded that suspected adverse reactions, including those associated with use of Acomplia, should be reported to the IMB either on-line on the IMB website at www.imb.ie or using the downloadable version of the adverse reaction report form also available from the IMB's website. Downloaded forms should be completed and sent by freepost to the IMB at "Freepost", Pharmacovigilance Section, Irish Medicines Board, The Earlsfort Centre, Earlsfort Terrace, Dublin 2. Alternatively, completed forms may be submitted by fax to (01) 6762517. Finally, post-paid report cards can be obtained directly from the Pharmacovigilance Section of the IMB at (01) 6764971.

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