sanofi aventis
Because health matters

14th July 2008

IMPORTANT SAFETY INFORMATION

Acomplia® (rimonabant) 20mg Film-Coated Tablet

Patients should be actively monitored for signs and symptoms of psychiatric disorders, particularly depression, following the start of treatment with Acomplia.

Sanofi-aventis, in agreement with the European Medicines Agency (EMEA) and the Irish Medicines Board, would like to inform you about important revised prescribing and safety information, for Acomplia (rimonabant) 20 mg film-coated tablet.

Acomplia is indicated "As an adjunct to diet and exercise for the treatment of obese patients (BMI≥ 30kg/m2), or overweight patients (> 27kg/m2) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia".

When Acomplia was introduced in 2006 the Summary of Product Characteristics (SmPC) and Package Leaflet (PL) included information concerning the risk of depression. Additionally, in July 2007 a contra-indication regarding major depressive illness and/or ongoing anti depressive treatment as well as warnings about depressive disorders was added to the product information (SmPC and PL) and healthcare providers were informed by letter.

As part of the continuous monitoring of the safety of Acomplia, spontaneous reports concerning psychiatric reactions such as depressive disorders including suicidality and aggressiveness have been analysed and the following recommendations have been added to the SPC.

New recommendation:
Depressive reactions may occur in patients who have no obvious risk factors, apart from obesity itself. In postmarketing experience, more than half of the patients who develop such reactions appear to do so within 1 month of starting treatment, approximately 80% appear to do so within 3 months. Patients should be actively monitored for signs and symptoms of psychiatric disorders, particularly depression, following the start of treatment. If depression is diagnosed during rimonabant therapy, rimonabant treatment must be stopped. The patient should be monitored and treated appropriately.

The information provided in this letter has been reviewed and endorsed by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA). The CHMP will continue to monitor the efficacy and safety of Acomplia.

Call for reporting
Any adverse events experienced by your patients should be reported to sanofi-aventis Ireland Ltd. and/or to the Pharmacovigilance Section of the IMB, in the usual way.

Communication information
Please review carefully the revised enclosed Summary of Product Characteristics and contact sanofi-aventis Ireland Ltd. if you have any additional questions or require any further information.

Address: Sanofi-aventis Ireland Ltd.
18 Riverwalk
National Digital Park
Citywest Business Campus
Dublin 24

Telephone: 01-4035600
Email address: IEmedinfo@sanofi-aventis.com

We remain at your disposal for any further information you may need.

Yours sincerely,

Dr. Anil S. Jina, MB BCh

Medical Director

Annexes:

Copy of the revised SmPC (with changes underlined)