sanofi aventis

Because health matters

27th July 2007

IMPORTANT SAFETY INFORMATION

Increased frequency of reports of depression in patients treated 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 should not be prescribed to patients with ongoing major depressive illness and/or ongoing treatment with antidepressants. Acomplia is indicated "As an adjunct to diet and exercise for the treatment of obese patients (BMI≥ 30 kg/m^2), or overweight patients (> 27 kg/m^2) with associated risk factor(s), such as type 2 diabetes or dyslipidaemia".

Depressive disorders or mood alterations with depressive symptoms have been reported in up to 10%, and suicidal ideation in up to 1% of patients receiving rimonabant. Further to the assessment of these data, the use of Acomplia has been restricted and the Summary of Product Characteristics (SmPC) has been amended as follows.

New recommendations:

- **Treatment of patients with ongoing major depressive illness and/or ongoing antidepressive treatment is contraindicated.**
- **Acomplia should not be used in patients with current suicidal ideation or with a history of suicidal ideation or depressive disorder unless the benefit of the treatment outweighs the risk in the individual patient.**
- **Treatment with Acomplia should be stopped if depression occurs.**
- **Patients and caregivers of patients should be informed about the risk of depression.**
- **Patients should be encouraged to stop treatment and seek medical advice if symptoms occur.**
- **Therapy with Acomplia is not recommended in patients with uncontrolled psychiatric illness other than depression.**

Call for reporting

Patient safety is the highest priority for sanofi-aventis and we are committed to ensuring that healthcare professionals continue to have the information necessary to prescribe Acomplia appropriately. Please review carefully the revised enclosed SmPC and contact sanofi-aventis if you have any additional questions. Any adverse events experienced by your patients should be reported to sanofi-aventis Ireland Ltd. directly or the Pharmacovigilance Section of the IMB, in the usual way.

Communication information

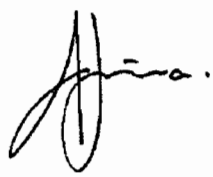
For further information please contact sanofi-aventis Ireland Ltd.

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

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