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IMPORTANT SAFETY INFORMATION FOR ZELNORM

June 01 2007

Dear Heath Care Professional:

Further to your previous enquires regarding Zelnorm/Zelmac **(tegaserod maleate) tablets,** Novartis is writing to inform you about important safety information and recent regulatory action in the US related to its use.

On Friday, March 30, 2007, Novartis complied with an FDA request to suspend marketing and sales of Zelnorm/Zelmac in the US while discussing with the FDA the best way to continue to make Zelnorm/Zelmac available to appropriate patients in the US.

Although Zelnorm/Zelmac is not approved for Marketing in Ireland or the EU, in view of your previous enquires relating to the product, we would like to share with you the safety data which led the FDA to request this course of action.

In clinical studies involving over 18,600 patients, there was a low incidence of cardiovascular ischemic events [13 of 11,614 (0.11%) for patients taking Zelnorm/Zelmac; 1 of 7,031 (0.01%) taking placebo, p=0.024]. Out of the 13 patients on tegaserod, 10 had a coronary ischemic event while three patients on tegaserod (and one on placebo) had a cerebrovascular accident.

All patients affected had pre-existing cardiovascular disease and/or CV risk factors. There was no pattern relative to the time of occurrence of these events and no association with dose. In addition, results obtained from multiple mechanistic studies do not suggest any arterial vasoconstrictive effect of tegaserod.

Novartis is working closely with health authorities to further investigate these results and consider appropriate regulatory action.

Novartis continues to believe in the benefits of Zelnorm/Zelmac when used in appropriate patients. As a risk minimization measure, Novartis proposes to restri t the use of Zelnorm/Zelmac as follows:

- Zelnorm/Zelmac should only be used in women below the ag 55.

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- Zelnorm/Zelmac should not be used in patients with cardiovascular ischemic disease and patients at increased risk for cardiovascular ischemic events, indicated by the presence of risk factors.

You should take this information into account when/if considering prescription of Zelnorm/Zelmac, as well as considering the recommendations of the overall prescribing information.

Novartis Pharma AG reiterates its commitment to the well-being of patients and the delivery of quality pharmaceutical products and is committed to ensuring the timely dissemination of new information that is important to physicians and patients.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of Zelnorm/Zelmac to the Irish Medicines Board or to Novartis at the below contact details.

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Yours sincerely,

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