Bayer

IMPORTANT DRUG WARNING

Pharmaceutical Division

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Vice President
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Re: Market withdrawal of Baycol (cerivastatin)

Dear Healthcare Professional:

I am writing to inform you of very important new safety information about Baycol (cerivastatin) and rhabdomyolysis.

Rhabdomyolysis is a serious, potentially fatal, adverse effect of all statin drugs, including Baycol. It can occur with statin monotherapy, though the risk appears to be increased significantly by concomitant use of gemfibrozil (Lopid).

Our ongoing scrutiny of post-marketing reports of rhabdomyolysis, including fatalities, has revealed an increased reporting rate of rhabdomyolysis with Baycol relative to other statins, especially when gemfibrozil is co-prescribed. These data also suggest an increased reporting rate of rhabdomyolysis at the 0.8 mg dose of Baycol alone.

Bayer Corporation has already placed a contraindication in the Baycol product prescribing information sheet against co-prescription with gemfibrozil and issued letters to healthcare professionals warning against co-prescription of these two drugs. Despite these and other actions, Bayer has continued to receive reports of rhabdomyolysis when gemfibrozil is prescribed as a co-medication. Since the co-prescription of Baycol and gemfibrozil has continued despite communications by Bayer against this practice, the company has decided to take the following voluntary action to prevent further cases of rhabdomyolysis:

Effective immediately, Bayer has discontinued the marketing and distribution of all dosage strengths of Baycol. Patients who are currently taking Baycol should have their Baycol discontinued and be switched to an alternative therapy.

Bayer is taking this action as part of an ongoing commitment to patients and their healthcare providers to ensure patient safety.

It is important that you forward any adverse event information associated with the use of Baycol to Bayer Corporation at 1-800-288-8371. You can also report the information directly to the FDA via the MedWatch system at 1-800-FDA-1088, by mail (using a postage paid form), or the internet at www.fda.gov/medwatch.

If you have further questions regarding this action on Baycol, please contact Bayer Customer Service at 1-800-758-9794.

Yours sincerely,

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