Bayer

IMPORTANT DRUG WARNING

August 8, 2001

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.

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 rhambdomyolysis at the 0.8 mg dose of Baycol alone.

Bayer Inc. has already placed a contraindication in the Baycol Product Monograph against co-prescription with gemfibrozil and communicated 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 Inc. at 1-800-265-7382. You can also report the information directly to Health Canada by fax at 613-957-0335.

If you have further questions regarding this action on Baycol, please contact Bayer Inc. at 1-800-265-7382.

Yours sincerely

original signed by

Neil S. Maresky, M.B., B.Ch.
Vice President
Medical and Scientific Affairs

Any suspected adverse drug reactions can be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Bureau of Licensed Product Assessment
Therapeutic Products Directorate
HEALTH CANADA
Address Locator: 0201C2
OTTAWA, Ontario, K1A 1B9
Tel: (613) 957-0337 or Fax: (613) 957-0335
Toll free lines for consumers & health profesionals Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

The ADR Reporting Form can be found in *The Canadian Compendium of Pharmaceuticals and Specialties*, or on the TPD web site, along with the ADR Guidelines at:

http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/forms/adverse_e.pdf
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