

Therapeutic Products Directorate Direction des produits thérapeutiques

Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD) posts safety alerts, public health advisories, press releases and other notices from industry as a service to health professionals, consumers, and other interested parties. Although TPD and BGTD approve therapeutic products, TPD and BGTD do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **BAYER INC.** Contact the company for a copy of any references, attachments or enclosures.

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.

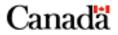
Our ongoing scrutiny of post-marketing reports of rhabdomyolysis, including fatalities, has revealed an increased reporting rate of rhabdomyolysis with Baycol relative to other statins, especially when gemfibrozil is co-prescribed. These data also suggest an increased reporting rate of rhambdomyolysis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

Bayer Inc. has already placed a contraindication in the Baycol Product Monograph against coprescription with gemfibrozil and communicated to healthcare professionals warning against coprescription 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 http://www.hc-sc.gc.ca/hpb-dgps/therapeut/zfiles/english/guides/adr/guideline_e.pdf