



QSM/MC/IEA.102

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Information Exchange System**Alert No. 102****Voluntary withdrawal of Cerivastatin – Reports of Rhabdomyolysis**

USA. Bayer Pharmaceutical Division has announced its decision to withdraw Baycol (cerivastatin) from the U.S market following reports of rhabdomyolysis, a severe muscle adverse reaction than can sometimes have fatal consequences. The FDA has agreed with and supported this decision.

Baycol (cerivastatin) was initially approved in the U.S. in 1997. It belongs to a group of cholesterol lowering drugs referred to as “statins”. While all statins could potentially cause this dangerous muscle reaction, rhabdomyolysis appears more frequent with cerivastatin, especially when used in high doses, in the elderly or, when taken along with gemfibrozil, another cholesterol lowering drug. In this connection it may be noted that Bayer has withdrawn all dosages of Baycol / Lipobay with immediate effect throughout the world (except in Japan where gemfibrozil is not available). The company is also withdrawing current market supplies of the product.

Lovastatin (Mevacor), pravastatin (Pravachol), simvastatin (Zocor), fluvastatin (Lescol) and atorvastatin (Lipitor) are five other statins that may be used as alternatives to cerivastatin.

References:

1. FDA Talk Paper T01-34, 8 August 2001.
2. Australian Adverse Drugs Reaction Bulletin 20:2, February 2001.