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Bromfenac (Duract®) - withdrawn from the market : severe liver failure

Wyeth-Ayerst, USA. The Food and Drug Administration has announced that the manufacturer has voluntarily withdrawn the nonsteroidal anti-inflammatory agent, bromfenac (Duract®: Wyeth-Ayerst). This action follows postmarketing reports of rare severe liver failure in patients who used the drug for extended periods of time, contrary to the instructions in the labelling.

Bromfenac was approved in 1997 for the short-term management of acute pain (10 days or less). It was not approved as a treatment for longer term use for chronic conditions such as osteoarthritis or rheumatoid arthritis.

No cases of serious liver injury were reported in clinical trials. However, because there was a higher incidence of liver enzyme elevations in patients treated long term in clinical trials, the product was approved for use for 10 days or less, and information about elevated liver enzymes was included in the product labelling.

After Duract® was marketed, the FDA and the company received several reports of cases of severe hepatitis and liver failure (some requiring transplantation) in patients taking the drug for more than 10 days. Consequently, a special black box warning was added to the labelling and the company issued a "Dear Doctor" letter emphasizing that patients should not take the drug for more than 10 days. [See WHO Pharmaceuticals Newsletter Nos. 3&4, March&April 1998]

Despite these actions, the FDA and the company continued to receive reports of severe injuries and death with long-term use of Duract®. Therefore, taking into consideration the availability of other therapies, the FDA and Wyeth-Ayerst concluded that it would not be practical to implement the restrictions necessary to assure safe use and that it would be prudent to withdraw the drug from the market.

Reference: FDA Talk Paper T98-36 dated 22 June 1998.

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