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PHA Information Exchange Service

ALERT No. 28

WORLDWIDE WITHDRAWAL OF TEMAFLOXACIN (OMNIFLOX®)

United States of America. The Food and Drug Administration has announced that the manufacturer of the quinolone antimicrobial agent, temafloxacin (Omniflox®: Abbott), has voluntarily withdrawn the product worldwide and halted all further distribution. This action has been taken because of reports of severe adverse reactions associated with the use of this drug in the first three months of marketing.

There have been a total of 50 reports of serious adverse reactions, including three deaths. Several reports cited cases of severe hypoglycaemia, especially in very elderly patients with decreased kidney function. Among the severe reactions there were a number of cases of an unusual complex of adverse reactions consisting of haemolytic anaemia (destruction of red blood cells) and other blood cell abnormalities. Also observed were patients with kidney dysfunction, about half of which required renal dialysis. Other patients suffered liver dysfunction. There have also been several reports of anaphylactic reactions, some of which have caused life-threatening respiratory distress.

Temafloxacin is one of a new class of synthetic oral quinolones - broad-spectrum antimicrobials - that are used to treat a variety of infections including lower respiratory tract infections, skin and skin structure infections, infections of the prostate and of the urinary tract. Other antibiotics of this class have not been reported to be associated with comparable numbers of serious adverse reactions.

Reference: HHS News P92-16, Food and Drug Administration, 5 June 1992.

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