DRUG ALERT

Pfizer withdraws Bextra in South Africa

Pfizer South Africa announced on 13 April 2005 that the company would suspend the sale of the oral Cox-2 inhibitor Bextra with immediate effect. The suspension is voluntary and at the request of the Medicines Control Council.

This suspension of sales does not stem from any new scientific information, but is a direct result of the request by the Council. While Pfizer respectfully disagrees with the Council decision and believes that Bextra is a valuable treatment alternative for the relief of short-term postoperative pain and primary dysmenorrhoea, the company will comply with the request pending investigation of the entire NSAID and Cox-2 class of medicines.

The Medicines Control Council request for a voluntary suspension follows a similar request from the US Food and Drug Administration and various other regulatory bodies, including the European Medicines Agency, EMEA. In coming to their decision, the FDA considered that unproven cardiovascular safety in long-term use, coupled with the possibility of severe skin reactions, led to an unfavourable risk-benefit profile. Bextra, which was launched in South Africa in August 2004, is only indicated for the treatment of acute, mild to moderate postoperative pain and primary dysmenorrhoea and not for long-term use in rheumatoid or osteoarthritis, as in the USA. Treatment typically runs for 5 days.

To this end, the following advice is offered:

Prescribers are advised not to initiate treatment in new patients and physicians should consider whether patients currently on Bextra should finish their current course of treatment while being monitored or be switched immediately to alternative therapeutic options.

Pharmacists are advised not to dispense further prescriptions for Bextra and to advise patients receiving Bextra to return to their doctors to discuss alternative therapeutic options. In addition, pharmacists are advised that stock will be withdrawn from their sites, through a withdrawal notification procedure.

Patients are advised to make an appointment with their health care providers to discuss their current treatment with Bextra and alternative treatment options.

For further drug-related information, please call Pfizer on 086 073 4937.