

**Bextra (valdecoxib) tablets**

**IMPORTANT NEW SAFETY INFORMATION**  
**CARDIOVASCULAR RISK**

February 2005

Dear Healthcare Professional

In December 2004, you received safety information about Bextra (valdecoxib) regarding the contraindication in Coronary Artery Bypass Graft Surgery and additional information on severe adverse skin reactions. On February 17<sup>th</sup> 2005 Pfizer, following a discussion with the European Medicines Agency (EMA) has revised the product labelling with important new Bextra safety information.

**Summary of the prescribing information and changes are outlined below:**

Bextra is indicated for symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and primary dysmenorrhoea.

- In osteoarthritis and rheumatoid arthritis: the recommended daily dose is 10 mg taken once daily. Some patients may receive additional benefit from 20 mg once daily. In the absence of increased therapeutic benefit after two weeks, other therapeutic options should be considered.
- For primary dysmenorrhoea: the recommended dose for symptomatic relief is 40 mg once daily as required. On the first day of treatment, an additional 40 mg dose may be taken if needed. Thereafter, the maximum recommended dose is 40 mg once daily.
- In all cases the patient's response to therapy should be re-evaluated periodically. The decision to prescribe Bextra should be based on an assessment of the individual patient's overall risk. Cardiovascular risks of treatment may increase with dose and duration of exposure, therefore the lowest effective daily dose should be used for the shortest duration possible.

**Bextra is now CONTRAINDICATED in patients with established ischaemic heart disease and/or cerebrovascular disease.** In addition is now contraindicated in class II-IV NYHA congestive heart failure. Bextra should also not be used in the treatment of post-operative pain following coronary artery bypass graft (CABG) surgery. **Bextra should not be prescribed to such patients.**

Patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) or peripheral arterial disease should only be treated with Bextra after careful consideration.

Physicians are advised to consider this new information when making the decision to prescribe Bextra.

The Product Information for Bextra has now been revised accordingly (see attached).

If you have any questions concerning this important safety information, please contact Pfizer Ltd. Medical Information at XXXXX.

Any suspected adverse drug reactions should be notified to the <MAH> and <name of national agency> in the usual away.

Yours Sincerely,

.....  
Medical Director