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DEAR HEALTHCARE PROFESSIONAL LETTER

Important safety information

Restrictions of use for piroxicam [Feldene™ Capsules] and new treatment recommendations, including new contraindications & special warnings

7th December 2007
FE_090

Dear Healthcare Professional,

Following the reassessment conducted recently by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) on the gastrointestinal and skin safety profile and the benefit/risk ratio of the Non-Steroidal Anti-Inflammatory Drug (NSAID) Piroxicam, we would like to bring to your attention new treatment recommendations and changes affecting the Summary of Product Characteristics (SPC) of all systemic formulations of piroxicam-containing medicinal products resulting from the above-mentioned assessment.

Physicians and patients should be fully aware of the potential risks of the treatment and should discontinue piroxicam treatment at the first sign or symptom of gastrointestinal or skin complications.

Key SPC revisions include:

THERAPEUTIC INDICATIONS HAVE BEEN RESTRICTED AS FOLLOWS:

- Piroxicam is no longer indicated in acute conditions, such as:
  - acute musculoskeletal disorders, acute gout, primary dysmenorrhoea and pain following orthopaedic, dental and other minor surgery.

  The restricted indications are:
  - Symptomatic relief of osteoarthritis, rheumatoid arthritis or ankylosing spondylitis.
- Piroxicam is not recommended as a first line option if an NSAID is indicated.
- The decision to prescribe piroxicam should be based on an assessment of the individual patient's overall risks and benefits.

POSOLOGY AND METHOD OF ADMINISTRATION HAVE BEEN MODIFIED IN LINE WITH THE RESTRICTED INDICATION AND TO INCLUDE THE FOLLOWING ADDITIONAL INFORMATION:

- The prescription of piroxicam should be initiated by physicians with experience in the diagnostic evaluation and treatment of patients with inflammatory or degenerative rheumatic diseases and the benefit/risk of treatment should be reviewed within 14 days. If continued treatment is considered necessary, this should be accompanied by frequent review.
- The maximum recommended daily dose is 20 mg.
- As with other NSAIDs, undesirable effects may be minimised by using the minimum effective dose for the shortest duration necessary to control symptoms.
- As epidemiological evidence from some observational studies suggests that piroxicam may be associated with a high risk of serious gastrointestinal toxicity, the possible need for combination therapy with gastro-protective agents (e.g. misoprostol or proton pump inhibitors) should be carefully considered, in particular for elderly patients.

THE CONTRAINDICATIONS SECTION HAS BEEN UPDATED TO INCLUDE THE FOLLOWING ADDITIONAL INFORMATION:

- Patient history of gastrointestinal disorders that predispose to bleeding disorders such as ulcerative colitis, Crohn's disease, gastrointestinal cancers and diverticulitis;
- Concomitant use with other NSAIDs, including COX-2 selective NSAIDs and acetylsalicylic acid at analgesic doses;
- Concomitant use with anticoagulants, such as warfarin;
- History of previous serious allergic drug reaction of any type, especially cutaneous reactions such as erythema multiforme, Stevens-Johnson syndrome, epidermal toxic necrolysis;
- Previous skin reaction (regardless of severity) to piroxicam, other NSAIDs and other medications.

THE INTERACTIONS SECTION HAS BEEN UPDATED TO INCLUDE THE FOLLOWING ADDITIONAL INFORMATION:

- Increased risk if gastrointestinal bleeding/ulceration with corticosteroids.
- Increased risk if gastrointestinal bleeding with anti-platelets agents and SSRIs.

FINALLY, SPECIAL WARNINGS AND PRECAUTIONS FOR USE HAVE BEEN REVISED IN LINE WITH THE ABOVE MENTIONED CHANGES:

The warnings and precautions have been extensively updated with the aim of providing information allowing the identification of patients at increased hazard of serious gastrointestinal and skin adverse events. Accordingly, relevant strategies to minimise the risk have been introduced. Please note that treatment should be immediately discontinued at the first appearance of cutaneous reactions or relevant gastrointestinal events.

Please refer to the revised Summary of Product Characteristics, attached herewith, for the full prescribing information, including the specific sections on **"THERAPEUTIC INDICATIONS", "POSOLOGY AND METHOD OF ADMINISTRATION"**, **"CONTRAINDICATION"** and **"SPECIAL WARNINGS AND PRECAUTIONS FOR USE"**.

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The above information will be useful to manage your patients appropriately when using piroxicam.

If you have any queries about this letter or want any additional information, please contact Pfizer Medical Information Department at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, United Kingdom. The following freephone number is available for contacting Medical Information during normal working hours as well as for out of hours medical emergencies: **1800 633 363**. Please ask for the Medical Information group.

Please report any suspected cases of adverse reactions in association with use of Feldene to the Pfizer Drug Safety Group, at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, United Kingdom or to the Irish Medicines Board in the usual way. Pfizer Limited UK can be contacted by freephone **1800 633 363**. Please ask for Drug Safety.

Thank you very much for your time and attention.

Yours sincerely,

Dr. John Farrell

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Feldene 10 mg capsules, Feldene 20 mg capsules