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ARCOXIA® (etoricoxib): revised dose recommendation for rheumatoid arthritis or ankylosing spondylitis

Dear Healthcare Professional,

This letter is to inform you of a revised dose recommendation for ARCOXIA (etoricoxib) film-coated tablet for rheumatoid arthritis (RA) or ankylosing spondylitis (AS).

Summary

The prescribing information for ARCOXIA has been updated to introduce a lower dose of 60 mg daily for patients with RA or AS, while retaining the existing 90 mg daily dose for patients not responding to the 60 mg dose.

Revised recommended dosage:

- Recommended dose is 60 mg once daily
- In patients with insufficient relief from symptoms, an increased dose of 90 mg once daily may increase efficacy
- Once the patient is clinically stabilised, down-titration to 60 mg once daily may be appropriate
- In the absence of therapeutic benefit, other treatment options should be considered

Background

Two clinical trials cited below assessed the efficacy and safety of etoricoxib 60 mg once daily for the treatment of RA and AS, including comparison with etoricoxib 90 mg:

- **Protocol 107:** *A Phase III, Two-Part, Randomized, Double-Blind, Placebo-Controlled Multicenter Trial to Assess the Relative Efficacy and Tolerability of Two Doses of Etoricoxib in Patients with Rheumatoid Arthritis*
- **Protocol 108:** *A Phase III, Two-Part, Randomized, Double-Blind, Active Comparator-Controlled, Multicenter Clinical Trial to Study the Relative Efficacy and Tolerability of Two Doses of MK-0663/Etoricoxib in Patients with Ankylosing Spondylitis*

From these trials, there is evidence that the 60 mg dose is effective in RA and AS; however, for some patients, the 90 mg dose will be more efficacious. It is not possible to predict which patients will benefit from the higher dose. Therefore the recommended starting dose for treatment of RA or AS has been reduced to 60 mg once daily, with the option to increase to a maximum of 90 mg once daily if necessary. This change has been approved by the Medicines & Healthcare products Regulatory Agency (MHRA).

Please find enclosed the updated Summary of Product Characteristics (SmPC), which is also published on the Electronic Medicines Compendium (<https://www.medicines.org.uk>).

Call for reporting

Please report suspected adverse reactions with this medicine to the MHRA through the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard.

Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: "FREEPOST YELLOW CARD"
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- Or by electronic download through the Yellow Card section of the MHRA website

When reporting a suspected adverse reaction, please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Company contact point

If you have any questions or require further information about ARCOXIA, please contact Grunenthal Medical Information on 0870 3518960 or via email to medicalinformationuk@grunenthal.com

Yours sincerely,



Dr Mark Toms
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(on behalf of the Marketing Authorisation Holder)



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