MERCK SHARP & DOHME
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M.O.H. License No.: 105/A

06Feb2017

MSD

DHPC

Subject: **Arcoxia – Product Strengths: 60, 90 & 120mg**

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 will be updated during this year 2017 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 stabilized, 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

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Information in this letter has been approved by the Saudi Food and Drug Authority. The Summary of Products Characteristics (SPC) and patient leaflet of Arcoxia dated on April 2016 is not including this lower dose, new SmPC will be submitted during this year 2017 to SFDA for an approval.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Center (NPC):
By email: npc.drug@sfda.gov.sa
Or by fax: +966 11 2057662
Or by online: https://ade.sfda.gov.sa/
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 MSD Medical Information on dpoc_saudi@merck.com or saudi.pharmacovigilance@merck.com

If you have distributed this product to another service or facility, please forward this information as appropriate.

We apologize for any inconvenience you may experience as a result of this communication.

If you have any questions, please contact Ula Alhumaidan, at the above mentioned Company contact point

Sincerely,

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Customer Reply Form

(Healthcare Professional letter dated *06Feb* 2017)

Please complete and return this form to the FAX number listed below as confirmation that you have received this notification. A fax cover sheet is not required.

F : +966114006484

Facility Name and Address :	
Reply Confirmation Completed By : *(Please print name)*	
Title : *(Please print)*	
Telephone Number (including Area Code) :	

We have received the above mentioned letter and have disseminated this information to our staff and to other services or facilities, as applicable.

☐ I do confirm receipt of DHCP notification related to Arcoxia –

☐ --

Signature/Date :
REQUIRED FIELD _____