PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT

Summary of risk management plan for ARCOXIA

This is a summary of the risk management plan (RMP) for Arcoxia. The RMP details important risks of Arcoxia, how these risks can be minimized, and how more information will be obtained about ARCOXIA's risks and uncertainties (missing information).

ARCOXIA's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ARCOXIA should be used.

Important new concerns or changes to the current ones will be included in updates of ARCOXIA's RMP.

I. The Medicine and What it is Used For

Arcoxia is authorized for the acute and chronic treatment of the signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA); treatment of ankylosing spondylitis (AS); treatment of acute gouty arthritis; relief of acute and chronic pain; treatment of primary dysmenorrhea; treatment of moderate to severe acute post-operative pain associated with dental surgery; treatment of moderate to severe acute post-operative pain associated with abdominal gynaecological surgery. It contains etoricoxib as the active substance and is given orally and each film coated tablet contains 30 mg, 60 mg, 90 mg, or 120 mg of etoricoxib.

II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of ARCOXIA, together with measures to minimise such risks and the proposed studies for learning more about ARCOXIA's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine’s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine’s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of Important Risks and Missing Information

Important risks of ARCOXIA are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of ARCOXIA. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

Table II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

The safety information in the proposed Prescribing Information is aligned to the reference medicinal product.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or are specific obligations for ARCOXIA.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for ARCOXIA.