Part VI: Summary of the risk management plan

Summary of risk management plan for Ibu Aristo 200 mg/400 mg/600 mg/800 mg and Ibu Aristo 200 mg/400 mg akut

This is a summary of the Risk Management Plan (RMP) for Ibu Aristo 200 mg/400 mg/600 mg/800 mg and Ibu Aristo 200 mg/400 mg akut. The RMP details important risks of the medicinal products and how more information will be obtained about their akut's risks and uncertainties (missing information).

Ibu Aristo 200 mg/400 mg/600 mg/800 mg and Ibu Aristo 200 mg/400 mg akut's SmPCs and its package leaflets give essential information to healthcare professionals and patients on how they should be used.

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

I. The medicine and what it is used for

Ibu Aristo 200 mg/400 mg/600 mg/800 mg is authorised for the symptomatic treatment of pain and inflammation in cases of:

- acute arthritis (including gout attack)
- chronic arthritis, especially in rheumatoid arthritis (chronic polyarthritis)
- ankylosing spondylitis (Bechterew's disease) and other inflammatory rheumatic diseases of the spine
- irritation in degenerative joint and spine diseases (osteoarthritis and spondylarthrosis)
- inflammatory, soft-tissue rheumatic diseases
- painful swelling and inflammation after injuries.

Ibu Aristo 200 mg/200 mg akut is authorised for the short-term symptomatic treatment of:

- mild to moderate pain such as headache, toothache, menstrual pain
- fever.

(see SmPC for the full indication).

Both medicinal productscontain ibuprofen as the active substance and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Ibu Aristo 200 mg/400 mg/600 mg/800 mg and Ibu Aristo 200 mg/400 mg akut, together with measures to minimise such risks and the proposed studies for learning more about the drugs' 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 analysed, 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 Ibu Aristo 200 mg/400 mg/600 mg/800 mg and Ibu Aristo 200 mg/400 mg akut 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 the products. 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).

List of important risks and missing information	
Important identified risks	Arterial thrombotic events such as myocardial infarction or stroke. Hypertension. Congestive Heart Failure and edema. Gastrointestinal effects-ulceration, bleeding perforation. Serious skin reactions. Hypersensitivity reactions including anaphylaxis reaction. Hepatic effects. Renal effects. Haematological effects. Aseptic meningitis. Medication overuse headache.
Important potential risks	Use during third trimester of pregnancy (including the risk of premature closure of patent ductus arteriosus, delayed labour, increased bleeding tendency). Use during first and second trimester of pregnancy. Use during lactation.
Missing information	None.

II.B Summary of important risks

The safety information in the proposed Product 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 which are conditions of the marketing authorisation or specific obligation of Ibu Aristo 200 mg/400 mg/600 mg/800 mg and Ibu Aristo 200 mg/400 mg akut.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Ibu Aristo 200 mg/400 mg/600 mg/800 mg and Ibu Aristo 200 mg/400 mg akut.