VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Rheumatic disease covers a variety of illnesses that cause symptoms musculoskeletal (joints, tendons and muscles) or from the connective tissue in blood vessels and internal organs.

The very broad definition of rheumatic disease means that most people at least once in their life has symptoms of a rheumatic disorder. Symptoms can range from transient neck or lower back pain or muscle or tendon soreness to more chronic diseases such as osteoarthritis, inflammatory arthritis or even life-threatening connective tissue diseases.

Arthritis can occur at any age. 10% of all has permanent or long lasting rheumatic disease, in people under 45 it is about 2%. Among the elderly, osteoarthritis of the hips, knees and fingers are common, while in younger back problems, arthritis of the tendons and muscles and inflammatory rheumatic diseases of the joints and connective tissue, dominates. Rheumatic disease is the predominant cause of long-term sick leave, and one in five health-related early retirement is due to a rheumatic disease, especially back problems and arthritis.

Rheumatic diseases can be divided into states of inflammatory reactions (inflammation) of the joints or connective tissue (20%), osteoarthritis (27%), back disorders (16%) and soft tissue rheumatism (pain in the muscles and tendons, 37%). In addition, the arthritis symptoms can be seen in the context of other medical conditions such as metabolic diseases, nerve disorders or in certain cases of cancer.

VI.2.2 Summary of treatment benefits

NSAID is an abbreviation of "Non Steroidal Anti-Inflammatory Drug. There is a wide variety of NSAIDs, includeing etodolac which are primarily used in the treatment of rheumatic diseases. NSAIDs attenuates tissue reactions (inflammation), which may be seen in these diseases - for instance the swollen joints or inflammatory conditions of connective tissue.

In arthritis treatment NSAIDs has eefct within a few days, but the drug does not affect the course of the disease in the long term. NSAIDs act as painkillers and reduce joint stiffness by inhibiting the formation of so-called prostaglandins, which cause inflammation and pain.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

Risk	**What is known**	**Preventability**
Allergy (Hypersensitivity reactions)	Hypersensitivity can occur in patients taking etodolac.	Etodolac should not be prescribed to patients who have previously shown

Risk	What is known	Preventability
		hypersensitivity reactions to etodolac or other NSAIDs. If hypersensitivity symptoms occur the product must be discontinued immediately.
Effects on the digestive system (Gastrointestinal bleeding or perforation)	Etodolac can cause bleeding, ulcers or holes (perforations) in the stomach and intestines that can lead to death. The risk of bleeding or perforations are higher: • With increasing doses of etodolac • In patients with a history of ulcers, especially when there is bleeding or perforation and in the elderly patients).	Etodolac should not be taken by patients who have ulcers and bleeding in the stomach or bowel. Patients should stop taking etodolac and contact their doctors if they experience pain in the upper part of the stomach and/or bleeding from the stomach or bowel while taking etodolac.
Severe hepatic or renal insufficiency	Use of NSAIDs may result in deterioration of kidney function. Those with the highest risk are patients with: • Impaired kidney function • Heart failure • Impaired liver function Patients treated with water pills (diuretics) Patients treated with blood pressure lowering medication (angiotensin converting enzyme inhibitors) Elderly patients Patients treated long-term with etodolac	The patient should inform the doctor about kidney and liver problems or about concomitant use of medicines such as water pills or blood pressure lowering drugs. Etodolac by patients with severe kidney or hepatic impairment.
Severe heart failure	Increased blood pressure and fluid retention in the body have been reported in association with NSAID therapy. Use of etodolac might be associated with a slightly higher risk of heart attack and stroke (condition that occurs when the blood supply to part of the brain is cut off). The risk is increased when etodolac is	Etodolac should not be taken by patients with severe heart failure. The patient should consult doctor if he/she has heart problems, previous history of stroke or are at high risk for this (for e.g. if he/she has high blood pressure, diabetes, high cholesterol or is a smoker). The

Risk	What is known	Preventability
	used for prolonged periods or used at higher doses.	recommended dose for treatment should not normally be exceeded.
Increased bleeding risk (Severe thrombocytopeni)	Etodolac like other NSAIDs, prevent blood clotting and has been shown to prolong bleeding time in normal individuals.	Etodolac should not be used in patients with severe reduction in platelet counts or who are taking blood thinning agents.
Third trimester of pregnancy	Etodolac, if administered to pregnant women during the last three months of pregnancy may expose foetus to heart and lung toxicity and kidney dysfunction. Etodolac should not be given to women during the last three months of pregnancy.	Etodolac should not be used during the last 3 months of pregnancy
Digestive system disease (Gastrointestinal disease)	Treating patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) should be done with care as treatment with NSAIDs can worsen these conditions.	Etodolac should not be taken – unless clearly indicated - by patients who have ulcerative colitis (a disease of the large intestine), Crohn’s disease, or ulcers in the stomach or bleeding more than once. The patients should also inform their doctors if they have or have had ulcerative colitis or Crohn’s disease.
Use during the first 6 months of pregnancy) First and second trimester of pregnancy	In the first 6 months of pregnancy, it should be used only if clearly needed and the dose should be kept as low and duration of treatment as short as possible.	In the first 6 months of pregnancy, etodolac should be used only if clearly needed and the dose should be kept as low and duration of treatment as short as possible.
Impairment of female fertility	The use of etodolac may reduce fertility and therefore should not be used in women who want to conceive. For women who have trouble conceiving or are undergoing investigation of infertility, withdrawal of etodolac should be considered.	Etodolac should not be used in women who want to become pregnant as it can reduce fertility. If treatment with etodolac is required, it should be short and with lowest dose possible.

Risk	What is known	Preventability
Use in children	Etodolac has not been tested in children and knowledge about the use in children is insufficient	Etodolac should not be used in children.

VI.2.5 Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Etodolac Alternova can be found on the webpages of the Agencies after the products have been approved.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not Applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not Applicable.