IBUMAX-C 400 mg/300 mg tablets, filmcoated

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PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Influenza and common cold are both viral infections. Common cold is an infection of the upper respiratory tract i.e. nose, throat and larynx. Flu can be caused by over 200 different viruses, rinovirus being the most important. Common cold is the most common acute human disease. Adults suffer from common cold on average 1-5 times a year, children up to 5-10 times a year. Typical symptoms of the common cold are runny nose, nasal congestion, cough, fever, hoarseness, muscle aches, sore throat and often a feeling of pressure in the sinuses.

Influenza is a respiratory infection caused by influenza viruses A and B. Influenza viruses cause annual epidemics that peak during winter in temperate regions. The symptoms are very similar to the common cold, however on average symptoms, particularly fever and muscle aches, are more severe. The risk of sequelae such as pneumonia caused by bacteria is greater in influenza than in common cold.

VI.2.2 Summary of treatment benefits

There is no healing treatment for the common cold, but its symptoms can be alleviated with medication. Ibuprofen reduces pain, inflammation and fever. Since it was first introduced in 1967, ibuprofen has become common medicines used for different pain conditions. Numerous clinical trials in adults and children have demonstrated the efficacy and tolerability profile of ibuprofen in the treatment of mild to moderate pain conditions.

Ascorbic acid can act as both a pro-oxidant and an antioxidant. In general, at low ascorbic acid concentrations, vitamin C is prone to be a pro-oxidant, and at high concentrations, it will tend to be an antioxidant. Ascorbic acid at high doses has been suggested to reduce the duration of common cold episodes.

Ibumax-C is indicated for temporary fever and pain conditions, such as the common cold or flu-related symptoms, muscle and joint pain and headache.

VI.2.3 Unknowns relating to treatment benefits

The elderly are at increased risk of serious consequences of undesirable effects. The lowest effective dose should be used and for the shortest possible duration.

Caution is recommended in patients with renal and hepatic impairment. Dose adjustment is not normally required in mild to moderate impairment. However, dose should be kept as low as possible. If possible Ibumax-C should not be used severe renal and/or hepatic impairment.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Arterial thrombotic events (MI and stroke) (at 2400 mg/day)	Medicines such as ibuprofen may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Patients who have heart problems, previous stroke or a risk of these conditions (for example high blood pressure, diabetes or high cholesterol or are a smoker) have a risk for these effects.	The risk can be minimized by using the lowest effective dose for the shortest duration necessary to control symptoms. Patients with risk factors should only be treated with ibuprofen after careful consideration. Patients should discuss with doctor or pharmacist before starting treatment.
Gastrointestinal perforation, ulceration and bleeding (PUB)	Gastrointestinal bleeding, ulceration and perforation have been reported in connection with ibuprofen treatment. It may occur without any warning signs even in patients who have never had such problems before. It may also be fatal.	Patients with the risk factors should commence treatment at the lowest possible dose. Patients, especially those with a history of gastrointestinal reactions and elderly, should monitor for any unusual abdominal symptoms (especially gastrointestinal bleeding), particularly at the start of the treatment and, if such symptoms occur, to discontinue treatment and seek medical help. Treatment with mucosa-protective drugs should be considered in patients with risks factors for gastrointestinal adverse effects.
Renal toxicity	There is a risk of kidney impairment in dehydrated children and adolescents.	Careful medical monitoring is needed and caution should be used when initiating ibuprofen treatment in patients with

Risk	What is known	Preventability
	Ibuprofen may impair kidney function. Patients at greatest risk of kidney damage are those who already have kidney, heart failure or liver problems, those taking diuretics and ACE inhibitors and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pre-treatment state.	considerable dehydration.
Cardio-renal effects	There is a possibility of fluid retention and impaired renal function when ibuprofen is used in patients with heart failure, renal or hepatic disease who are on diuretics.	The product should not be used in patients who are at risk for cardio-renal effects.
Prolonged bleeding time/coagulation disorders	Ibuprofen use may increase the risk of bleeding.	The product should not be used in patients who have increased risk of bleeding.
Bronchospasm in patients with asthma or allergic disease	Ibuprofen has been reported to cause narrowing of the airways with difficulty in breathing (bronchospasm) in asthmatic patients and in patients with a previous history of bronchial asthma or allergic disease.	Patients who have previously had asthma or hypersensitivity reactions taking medicines containing acetylsalicylic acid (such as aspirin) or other drugs for pain and inflammation (NSAIDs) should not take Ibumax-C.
Serious skin reactions including Stevens Johnson syndrome and toxic epidermal necrolysis	Ibuprofen may very rarely cause serious skin reactions some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis. The highest risk of these reactions is within the first month of treatment.	Early signs should be monitored. Ibumax-C should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.
Hepatic disorders	Ibuprofen may very rarely cause hepatic impairment in long term treatment.	The aim is treatment with lowest possible dose and duration. In long term use liver function

Risk	What is known	Preventability
		should be monitored.
Hypersensitivity reactions in patients with previous hypersensitivity reactions to NSAIDs or aspirin	Ibuprofen may cause severe hypersensitivity and allergic reactions (anaphylaxis).	Early signs should be monitored and medication discontinued in case of them. The product should not be used in patients with known hypersensitivity to salicylates, NSAID or excipients of the Ibumax-C tablet.
Premature closure of the foetal ductus arteriosus (use during third trimester of pregnancy)	Ibuprofen may expose fetus to cardio-pulmonary toxicity and renal dysfuction and mother and neonate to prolonged bleeding time and delayed or prolonged labour.	The product should not be used in last trimester of pregnancy.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Foetal cardiac malformation, gastroschisis and miscarriage (use during early pregnancy)	Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data of epidemiological studies suggest an increased risk of miscarriage and of cardiac, malformations and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformations was increased from less than 1% up to about 1.5%. The risk is believed to increase with dose and duration of therapy.

Missing information

Risk	What is known
Use during breast feeding	Ibuprofen is only excreted in small amounts in breast milk. According to the current information it can be used during breast feeding if necessary. However, information of the clinical effects of ibuprofen use during breast feeding are monitored.

VI.2.5 Summary of 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.

VI.2.6 Planned post authorisation development plan

Not applicable

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable. This is the first version of the risk management plan for Ibumax-C.