PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

BURANA 400 MG POWDER FOR ORAL SOLUTION IN SACHET

ORION OYJ

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VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Burana 400 mg powder for oral solution is indicated to be used to relief mild to moderate, temporary pain and fever, for example common cold caused by viruses, muscle- and joint pain, headache (including migraine headache), dental-, rheumatism- and menstrual pain.

Pain is a complex biological phenomena that can be caused by multiple diseases and conditions. Examples of different pain conditions include post-operative pain, pain due to musculoskeletal disease states, pain due to traumas and cancer-related pain.

A fever is a body temperature that is higher than normal. Fever is a way of the body to react to some abnormal situations, most often infections. It is part of the body's defence against infection. Most bacteria and viruses that cause infections do well at the body's normal temperature but a slight fever can make it harder for them to survive. Fever also activates the immune system. Infections cause most fevers but there can be many other causes, such as medicines, cancers and autoimmune diseases.

The exact prevalences of pain and fever are difficult to assess but they are very common symptoms and sometimes interrelated, as well as associated with inflammation.

VI.2.2 Summary of treatment benefits

Pain can be harmful or even restricting for the patient. Pain decreases the quality of life of a patient and can also restrict her/his ability to work. Thus, appropriate and effective treatment of pain is important. Prolonged high fever can be harmful for the body and in those cases it is important to lower the fever.

The active substance in Burana 400 mg powder for oral solution is ibuprofen, which inhibits the formation of substances that mediate pain, inflammation and fever in the body. Therefore, many symptoms can be treated simultaneously by ibuprofen.

Since painkillers, as any medicines, can cause adverse effects the treatment with painkillers should optimally be only for short-term and the drugs should be used in the lowest doses that are effective.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Adverse effects in stomach and intestines	It is known that the use of Ibuprofen may cause ulcer and bleeding in stomach or intestines. This can sometimes be fatal. Patients with increased risk of ulcer and bleeding are elderly patients, patients with a history of ulcer and patients who are using ibuprofen with high doses and for a long time.	The patients, especially those with high risk of ulcer and bleeding, can be treated with the lowest possible dose. Concomitant use of protective medication should be considered. Patients with high risk of ulcer and bleeding should be monitored closely, particularly in the initial stages of treatment, so that ulcer or bleeding is detected as early as possible. Additionally, treatment with ibuprofen should be stopped if bleeding in stomach or intestines occurs during the treatment.
Adverse effects in heart and blood vessels	The use of ibuprofen, particularly at a high dose (>2400 mg daily) and in long-term treatment can be associated with a small increased risk of myocardial infarction or stroke. In patients with a history of increased blood pressure, impaired function of the heart or other heart-related diseases there is a risk for adverse effects of the heart and/or blood vessels with the use of ibuprofen. Other risk factors include abnormally elevated levels of lipids in the blood, diabetes mellitus and smoking.	Patients with risk factors for adverse effects in heart and/or blood vessels should only be treated with ibuprofen after careful consideration. Similar consideration should be made before initiating long-term treatment of patients with predisposing risk factors. These patients should be appropriately monitored and advised.
Hypersensitivity and allergic reactions	Patients who are allergic to ibuprofen or to any of the excipients may experience allergic reactions when treated with Burana 400 mg powder for oral solution.	Patients who know that they are allergic to ibuprofen should inform their physicians about the hypersensitivity. In addition, ibuprofen should be used with caution in patients with asthma and other previous hypersensitivity reactions.
Impaired renal function	Ibuprofen can decrease the function of the kidneys,	When treating patients with impaired function of the kidneys

Risk	What is known	Preventability
	especially in patients with renal impairment.	caution should be taken with the dosage of ibuprofen and the dosage should be assessed individually. The dose should be kept as low as possible and the function of the kidneys should be monitored. Patients with severe renal impairment should not use ibuprofen.
Increased risk of bleeding	Use of ibuprofen can increase the risk of bleeding.	Patients with a history of a disease in stomach or intestines and patients whose blood does not clot normally should be treated with care and be closely monitored during treatment. The lowest effective dose should be used for the shortest duration necessary to control symptoms.
Aseptic meningitis	Aseptic meningitis (inflammation of the thin tissue that surrounds the brain and spinal cord) has been observed on rare occasions in patients on ibuprofen therapy.	Physicians should carefully consider the need for the treatment and monitor the patients with systemic lupus erythematosus and related diseases, closely for symptoms.
Use during late pregnancy	When used in the late pregnancy, ibuprofen may cause adverse effects to the foetus, increase the risk of bleeding and prolong labour.	Ibuprofen should not be used during the last trimester of pregnancy.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Use during early pregnancy	Use of ibuprofen during early pregnancy may adversely affect the pregnancy and/or the development of the foetus. During the first and second trimester of pregnancy, ibuprofen should not be used unless clearly necessary. If it is considered necessary, the dose should be as low as possible for the shortest duration necessary to control the symptoms.
Lactation	Ibuprofen is excreted in breast milk but with normal doses and short-term use, it is unlikely that it affects the infant. If ibuprofen is prescribed for a long-term treatment, early weaning should be considered. All in all, the use of ibuprofen during lactation should be carefully considered.
Hepatic impairment	Ibuprofen may adversely affect the function of the liver, especially in

Risk	What is known (Including reason why it is considered a potential risk)
	patients with hepatic impairment. Treating patients with mild to moderate hepatic impairment the dose should be kept as low as possible for the shortest duration necessary to control the symptoms and the liver function should be monitored. Ibuprofen should not be used for patients with severe hepatic failure.

Important missing information

Risk	What is known
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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.

The Summary of Product Characteristics and the Package leaflet for Burana 400 mg powder for oral solution can be found in the national authority's web page.

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.