PUBLIC SUMMARY OF RISK MANAGEMENT PLAN (RMP)

MEDITUS 200 MG EFFERVESCENT TABLET

ORION OYJ

DATE: 10-05-2016, VERSIO 1.2

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Breathing is a complex process. The fine hairs (cilia) that line the upper airways may not trap all of the germs we breathe in. These germs can cause an infection in the bronchial tubes (bronchitis) or deep in the lungs (pneumonia). These infections cause a build-up of mucous or fluid that narrows the airways and limits airflow in and out of the lungs.

Chronic bronchitis occurs if the lining of the bronchial tubes is constantly irritated and inflamed. It causes a cough that often brings up mucous, as well as shortness of breath, wheezing, and chest tightness. The most common cause of chronic bronchitis is smoking cigarettes. Air pollution and dust or toxic gases in the environment or workplace also can contribute to the condition. The signs and symptoms may include – cough, production of mucous (sputum), which can be clear, white, yellowish-gray or green in color (rarely, it may be streaked with blood), fatigue, shortness of breath, slight fever and chills and chest discomfort.

Chronic obstructive pulmonary disease (COPD) is a lung disease that is characterised by a persistent blockage of airflow from the lungs. It is an under-diagnosed, life-threatening lung disease that interferes with normal breathing and is not fully reversible. Globally, ~10% of people older than 40 have moderate or worse airflow limitation; up to 25% may have mild airflow limitation. Undiagnosed are approximately 60-85% of people with COPD (mostly mild/moderate severity). Besides tobacco smoking, second-hand smoke, air pollution and work exposures to fumes and dusts cause COPD in susceptible people. COPD is the 4 th leading cause of death worldwide; its mortality is rising, while cardiovascular disease's is falling; COPD is expected to be the 3 rd leading cause of death over the next 20 years.

VI.2.2 Summary of treatment benefits

Meditus makes it easier to cough up mucous, i.e. it belongs to the group of mucolytics. Meditus effervescent tablets are used in connection with respiratory conditions which produce thick sputum.

In long-term use of acetylcysteine for patients with chronic bronchitis, it reduced the rate and severity of exacerbations thus reducing the number of days when the patient was unable to work.

VI.2.3 Unknowns relating to treatment benefits

Efficacy of treatment periods longer than 6 months has not been documented.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Safety in children aged < 2 years	Drugs like acetylcysteine which causes lysis or loosening of mucus, may obstruct the airways in children below 2 years of age due to the physiological characteristics of	Meditus should not be used in children under 2 years of age.

Risk	What is known	Preventability
	the airways in this age group. In addition, ability to cough up mucus may also be limited in this age group.	
Severe allergic reactions including a serious, potentially life-threatening allergic response marked by swelling, hives, lowered blood pressure, and dilated blood vessels (Severe hypersensitivity reactions including anaphylactic shock)	Severe allergic reactions have been reported with the use of acetylcysteine.	Meditus should not be used if a person is allergic to acetylcysteine or any of the other ingredients of this medicine.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Severe skin reactions including rare, life-threatening skin conditions that are either immune-complex–mediated hypersensitivity reactions or caused by a reaction to drugs (Severe skin reactions including Stevens Johnson Syndrome [SJS] and toxic epidermal necrolysis [TEN])	Serious skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome or TEN have very rarely been reported in temporal connection with the use of acetylcysteine. In most cases, at least one other suspect medicinal product, which was more likely the cause of the mucocutaneous syndrome could be identified. If cutaneous or mucosal alterations newly occur, immediate medical advice should be sought and the treatment with acetylcysteine should be discontinued immediately.
Clinical effects resulting from hindrance of blood clotting and platelet-inhibiting properties of acetylcysteine (Clinical effects resulting from anticoagulant and platelet-inhibiting properties of acetylcysteine)	A decrease in platelet aggregation in the presence of acetylcysteine has been confirmed in various studies. The clinical significance of this has not been determined.

Missing information

Risk	What is known
Use in pregnant and lactating women	There is limited data about the use of acetylcysteine in pregnant women. Animal studies do not indicate reproductive toxicity. Acetylcysteine crosses the placenta. Available data do not indicate a risk to the child. If necessary, the use of Meditus effervescent tablets during pregnancy may be considered. It is not known whether acetylcysteine passes into human milk, but at therapeutic doses, no effects of acetylcysteine are expected on the infant. Meditus effervescent tablets may be used during lactation.

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 Medituscan be found in the national authority's web page.

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.