Medipekt 1,6 mg/ml oral solution

17.6.2015, version 1.1

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Bromhexine is a mucolytic agent used in the treatment of respiratory disorders associated with viscid or excessive mucus/phlegm. Certain conditions such as acute bronchitis (affects about 44 out of every 1000 adults annually) causes a buildup of mucus/phlegm leading to chest congestion and a chesty, or congested cough. The mucus in lungs is held together by certain bonds. Mucolytics work by breaking these bonds. When these bonds are broken, the mucus becomes less sticky or less thick and is easier to cough up. This may also have a knock-on effect of making it harder for bacteria (germs) to infect the mucus and cause infections.

VI.2.2 Summary of treatment benefits

In clinical studies, bromhexine has been found to have mucus loosing effects in the respiratory tract, facilitating clearance of the phlegm and expectoration. Although the effect is often observed on the first treatment day already, good therapeutic effect is achieved in 3 to 5 days.
The use of bromhexine increases concentrations of antibiotics (amoxicillin, erythromycin and oxytetracycline) in the sputum and bronchopulmonary secretion.

VI.2.3 Unknowns relating to treatment benefits

Safety of bromhexine use during lactation has not been established.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Hypersensitivity reactions	Serious skin reactions, like Stevens-Johnson's syndrome and toxic epidermal necrolysis (TEN), have been reported, yet in only a couple of cases. These skin reactions were temporally connected with the use of expectorants /mucolytics, such as bromhexine. The reactions were mostly due to an effect by an underlying disease or concomitantly used medicines. In the initial phase of Stevens-Johnson's syndrome or toxic epidermal necrolysis, the patient may also first experience initial	If the patient experiences new kinds of skin or mucous membrane changes, (s)he must immediately contact a physician and stop the use of bromhexine as a precaution.

Risk	What is known	Preventability
	non-specific influenza-like symptoms, such as fever, pain all over the body, nasal stuffiness, cough, and sore throat. As non-specific influenza-like initial symptoms may be misleading, symptomatic treatment may be started with expectorants/mucolytics and flu medications.	

Risk	What is known	Preventability
Use in patients with ulcer disease	Bromhexine should be used cautiously if the patient has been diagnosed with gastric or duodenal ulcer because bromhexine may affect the protective mucosa in gastrointestinal tract.	If the patient has been diagnosed with gastric or duodenal ulcer, physician should be consulted before using bromhexine preparations.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Long-term use	When using bromhexine preparations it should be taken into account that continuous use of bromhexine may maintain abundant production and clearance of bronchial phlegm. Long-term use of the preparations is therefore recommended on physician's prescription only.

Missing information

Risk	What is known
Use during lactation	It is not known whether bromhexine or its metabolites are excreted in human milk. Pharmacodynamic and toxicological data on test animals show secretion of bromhexine and its metabolites in animal milk. A risk to the infants cannot be excluded. Bromhexine preparations should not be used during breastfeeding.

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 [invented name] can 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.