VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Productive cough is one of the main symptoms of acute bronchitis. Acute bronchitis is affecting approximately 5 % of adults per year. With 6.2 % of affected children annually, it is the most common infection reported in children aged 0-14 years. In general, there is a higher incidence observed during winter and fall compared to summer and spring.

VI.2.2 Summary of treatment benefits

The efficacy of thyme herb and primula root preparations for the treatment of productive cough has been demonstrated in several clinical studies and trials. Studies performed by Bionorica confirm that the combination of thyme herb and primula root can effectively treat cough symptoms. The herbal medicinal product Bronchipret TP film-coated tablets which contains thyme herb and primula root extracts as active ingredients has been investigated in clinical trials in the indication "acute bronchitis with productive cough" for a treatment duration of up to 14 days and has been shown to be effective with a favorable safety profile.

No special risks are known for the single active ingredients or for their combination. Considering the high number of marketed packages since 1993, the frequency of side effects is very low. Therefore the use of the fixed combination of thyme herb and primula root can be designated as safe.

Overall, the favorable toxicological and safety profile of Bronchipret combined with the proven efficacy of thyme herb and primula root in the indication productive cough demonstrate a positive benefit-risk balance for Bronchipret TP.

VI.2.3 Unknowns relating to treatment benefits

In the main study nearly all patients were caucasian; patients' ages ranged from 18 to 84 years (mean 42.7). There is no evidence to suggest that results would be any different in non-caucasian patients or in other age groups.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Hypersensitivity reactions such as rash, urticaria, swelling of face, mouth and/ or pharynx, dyspnoea	Frequency: very rare In general, symptoms are expected to be of mild to moderate intensity. More pronounced symptoms may require extended medical treatment.	Patients who are allergic (hypersensitive) to the active substances, to other plants of the Lamiaceae family or any of the other ingredients of this medicine must not take this medicinal product. In case of first signs of a hypersensitivity reaction this medicinal product must not be taken again.

Risk	What is known	Preventability
Gastrointestinal disorders such as cramps, nausea, vomiting and diarrhoea	Frequency: uncommon In general, gastrointestinal disorders are mostly of mild to moderate intensity and will abate without further medical treatment in most cases.	Patients who suffer from gastritis or gastric ulcer must not take this medicinal product without consulting a physician. This medicinal product contains glucose and lactose. Patients who have been told by their doctor that they have an intolerance to some sugars, should contact their doctor before taking this medicinal product.

Important potential risks

None.

Missing information

Risk	What is known
Use in children under 12 years of age	The use in children under 12 years of age has not been established because there is no adequate data in this age group.
Use during pregnancy or lactation	Safety during pregnancy and lactation has not been established due to the absence of sufficient data.

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.

There is no need for additional 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

Version	Date	Safety Concerns	Comment
1.0	29-Mar-2016	-	Initial RMP

2.0	04-Nov-2016	None	Updated in response to RMS Day 70 Preliminary Assessment Report (DE/H/4708/001/DC): Part VI: Amendment of Module VI.2.2 regarding the public summary of treatment benefits