RISK MANAGEMENT PLAN - PART VI

SUMMARY OF THE RISK MANAGEMENT PLAN

Active substance(s) (INN or common name)	**Ipratropium bromide**
Product's concerned (Brand name(s))	**LOMUSPRAY®**
Name of Marketing Authorization Holder or Applicant	**Sanofi A/S**
Data lock point (DLP) for this module	**31-JAN-2018**
Version number of Risk Management Plan (RMP) when this module was last updated	**Version 1.1 (DK)**

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ABBREVIATIONS

DLP:	Data Lock Point
INN:	International Nonproprietary Name
RMP:	Risk Management Plan
SmPC:	Summary of Product Characteristics

Summary of risk management plan for LOMUSPRAY (Ipratropium bromide)

This is a summary of the RMP for LOMUSPRAY. The RMP details important risks of LOMUSPRAY how these risks can be minimized.

LOMUSPRAY summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how LOMUSPRAY should be used.

Important new concerns or changes to the current ones will be included in updates of LOMUSPRAY's RMP.

VI.1. THE MEDICINE AND WHAT IT IS USED FOR

LOMUSPRAY is authorized for symptomatic relief of rhinorrhea (watery hypersecretion) at rhinitis (see SmPC for the full indication). It contains ipratropium bromide as the active substance and it is given by nasal route of administration.

VI.2. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMIZE OR FURTHER CHARACTERIZE THE RISKS

Important risks of LOMUSPRAY, together with measures to minimize such risks and the proposed studies for learning more about LOMUSPRAY's risks, are outlined in the next sections.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals.

Together, these measures constitute routine risk minimization measures.

VI.2.1. List of important risks and missing information

Important risks of LOMUSPRAY are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely administered or taken. Important risks can be regarded as identified or potential. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation.

Table 1 - List of important risks and missing information

Important identified risks	Glaucoma Atrial fibrillation
Important potential risks	None
Missing information	None

VI.2.2. Summary of important risks

Table 2 - Important risks and missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any – Important identified risk: Glaucoma

Important identified risk: Glaucoma	
Evidence for linking the risk to the medicine	Class effect of anticholinergic drugs Literature (1)(2)(3)(4)(5)(6)(7)
Risk factors and risk groups	Risk groups and risk factors are old age of concerned patients, and co-morbidities in individuals predisposed with narrow angles of the anterior chamber, increased intra-ocular pressure, myopia, family history and systemic diseases, auto-immune disease, and thyroid defect. Drugs that cause or exacerbate open-angle glaucoma are mostly glucocorticoids. Several classes of drugs, including adrenergic agonists, cholinergics, anticholinergics, sulpha-based drugs, selective serotonin reuptake inhibitors, tricyclic and tetracyclic antidepressants, anticoagulants, and histamine H1 and H2 receptor antagonists, have been reported to induce or precipitate acute angle-closure glaucoma, especially in individuals predisposed with narrow angles of the anterior chamber.
Risk minimization measures	Routine risk minimization measures SmPC: Labelled in sections 4.2, 4.4 and 4.8 Additional risk minimization measures None

SmPC: Summary of Product Characteristics.

Table 3 - Important risks and missing information with corresponding risk minimization activities and additional pharmacovigilance activities if any – Important identified risk: Atrial fibrillation

Important identified risk: Atrial fibrillation	
Evidence for linking the risk to the medicine	Class effect of anticholinergic drugs (8)(9)(10)(11)(12)(13)(14)(15)(16)(17)(18)
Risk factors and risk groups	The risk of developing atrial fibrillation increases with age, male sex, structural cardiovascular disease, such as myocardial infarction, congestive heart failure, valve disease and rheumatic heart disease, hypertension, and diabetes mellitus. Recent data suggests that genetic predisposition, inflammation, metabolic syndrome, excessive alcohol consumption, and obesity may also increase the risk of developing atrial fibrillation, especially in otherwise healthy individuals. Atrial fibrillation is associated with an increased long-term risk of heart failure and stroke. Furthermore, tachycardia/bradycardia, or sometimes a “brady-tachy syndrome”, can be associated with atrial fibrillation.
Risk minimization measures	Routine risk minimization measures SmPC: Labelled in section 4.8 Additional risk minimization measures None

SmPC: Summary of Product Characteristics.

VI.2.3. Post-authorization development plan

VI.2.3.1. Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of LOMUSPRAY.

VI.2.3.2. Other studies in post-authorization development plan

There are no studies required for LOMUSPRAY.