VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Bronchitis is an inflammation of the mucous membranes of the bronchi (the larger and medium-sized airways that carry airflow from the trachea into the more distal parts of the lung). Bronchitis can be divided into two categories: acute and chronic. Acute bronchitis is characterized by the development of a cough or small sensation in the back of the throat, with or without the production of sputum (mucus that is expectorated, or "coughed up", from the respiratory tract). Acute bronchitis often occurs during the course of an acute viral illness such as the common cold or influenza. Chronic bronchitis, a type of chronic obstructive pulmonary disease (COPD), is characterized by the presence of a productive cough that lasts for three months or more per year for at least two years. Chronic bronchitis usually develops due to recurrent injury to the airways caused by inhaled irritants. Cigarette smoking is the most common cause.

The main symptom of bronchitis is a hacking cough. It is likely that your cough will bring up thick yellow-grey mucus, although this does not always happen. The cough may last for several weeks after other symptoms have gone, and you may find the continual coughing makes your chest and stomach muscles sore.

VI.2.2 Summary of treatment benefits

Treatment for acute bronchitis is primarily symptomatic. ***Non-steroidal anti-inflammatory drugs*** (NSAIDs) may be used to treat fever and sore throat. Evidence suggests that the decline in lung function observed in chronic bronchitis may be slowed with smoking cessation. Chronic bronchitis is treated symptomatically and may be treated in a non-pharmacologic manner or with pharmacologic therapeutic agents. Wheezing and shortness of breath can be treated by reducing ***bronchospasm*** (reversible narrowing of smaller bronchi due to constriction of the ***smooth muscle***) with ***bronchodilators*** such as inhaled ***long acting β_2-adrenergic receptor agonists*** (e.g., ***salmeterol***) and inhaled ***anticholinergics*** such as ***ipratropium bromide*** or ***tiotropium bromide***. A mucolytic agent is an agent which dissolves thick ***mucus*** and is usually used to help relieve respiratory difficulties. It does so by dissolving various chemical bonds within secretions, which in turn can lower the viscosity by altering the mucin-containing components. Alternatively, attacking the affinity between secretions and the biological surfaces is another avenue, which is used by ***abhesives*** and ***surfactants***. Any of these effects could potentially improve airway clearance during coughing.

VI.2.3 Unknowns relating to treatment benefits

There is limited or no information about the use of acetylcysteine during pregnancy and lactation. As there is insufficient data from the use of acetylcysteine in pregnant and breast-feeding women, this medicinal product should not be used. Acetylcysteine has been clinically available since last few decades. It is one of the commonly known expectorant medications and as such the treatment benefits for acetylcysteine are well established in the indicated population.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Anaphylactic reactions and anaphylactic shock	Acetylcysteine can cause allergic reactions such as itching, skin rash, and hives and in very rare cases; it can cause severe skin reactions which requires medical intervention.	Yes: • Patients with history of allergic reaction to acetylcysteine or to any of the excipients should not be treated with acetylcysteine

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Stevens-Johnson syndrome and Lyell syndrome	Very rare cases of severe skin reactions such as Stevens-Johnson syndrome and Lyell's syndrome have been reported in connection with use of acetylcysteine. If new changes occur in the skin or mucous membranes, the physician should be contacted immediately and treatment with acetylcysteine should be discontinued.

Missing information

Risk	What is known
None	Not applicable

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a 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 (PIL). The measures in these documents are known as routine risk minimisation measures.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

Acetylcysteine containing products have been on the market for many decades; therefore, their efficacy and safety profile is well established. There is no planned post authorisation development program.

VI.2.7 Summary of changes to the Risk Management Plan over time

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
This is the first RMP for this product.	Not applicable	Not applicable	Not applicable