VI.2 Elements for a Public Summary

<BUDESONIDE AL> 0.25 mg Nebuliser Suspension

<BUDESONIDE AL> 0.5 mg Nebuliser Suspension

<BUDESONIDE AL> 1 mg Nebuliser Suspension

VI.2.1 Overview of disease epidemiology

Asthma
Asthma is one of the most common chronic diseases worldwide. It is a chronic inflammatory disease of the airways characterized by variable and recurring symptoms, reversible airflow obstruction, and bronchospasm.
Asthma is a common disease with high economic impact in both high- and lower-income countries. Current epidemiological data from the Global asthma report show that asthma affects 235 million people worldwide and that the prevalence is rising. The economic costs of asthma are among the highest for non-communicable diseases because of the substantial health service use, in many cases over a lifetime.

Chronic obstructive pulmonary disease (COPD)
Chronic obstructive pulmonary disease is a chronic inflammatory lung disease that causes obstructed airflow from the lungs.
COPD is responsible for early mortality and high death rates. In future COPD will be the third leading cause of death worldwide and fifth leading cause of years lost through early mortality or handicap.
This disease is also associated with significant comorbidities. COPD is a disorder that includes various phenotypes, the continuum of which remains under debate.

Pseudocroup (laryngitis subglottica)
Acute laryngotracheobronchitis (croup) is a common cause of acute upper airway obstruction in childhood. It It accounts for about 5% of hospital admissions in this population. Croup affects about 15% of children, and usually presents between the ages of 6 months and 5–6 years.
Croup refers to an infection of the upper airway, which obstructs breathing and causes a characteristic barking cough.
The cough and other symptoms of croup are the result of swelling around the vocal cords (larynx), windpipe (trachea) and bronchial tubes (bronchi). When a cough forces air through this narrowed passage, the swollen vocal cords produce a noise similar to a seal barking.

VI.2.2 Summary of treatment benefits

Budesonide AL is a nebuliser suspension which contains the active substance budesonide. This belongs to a group of medicines called “corticosteroids”.

Budesonide AL is used for treatment of lung diseases such as asthma, chronic obstructive pulmonary disease (COPD), and very serious pseudocroup during hospitalisation, when the use of pressurised or dry powder inhalers is not appropriate

Budesonide AL suspension is NOT indicated for the relief of acute bronchospasm (tightening of the muscles in the airways that causes wheezing) and breathlessness (apnoea).

When you inhale Budesonide AL, it enters directly into your lungs and reduces and prevents swelling and inflammation in your lungs.

VI.2.3 Unknowns relating to treatment benefits

Not applicable

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Systemic corticosteroid effects (systemic means that the medicine is carried throughout the body in the bloodstream from the site of application and have general rather than only local effects)	The following side effects have been reported: • Suppression of the adrenal gland (a small gland next to the kidney) can occur. The major symptoms of adrenal suppression include headaches, tiredness, feeling and being sick, weight loss, stomach pains and lack of appetite. • Feeling restless, nervous and irritable (these effects are more likely to occur in children). • Decrease in bone mineral density (thinning of the bones). • Glaucoma (increased pressure in the eye), aggression, sleeping problems and excitability • Anxiety • Depression • Clouding of the lens in the eye (Cataract)	The dose of inhaled corticosteroid should be titrated to the lowest dose at which effective control of asthma is achieved. Patients should always use this medicine exactly as the doctor has prescribed. Patients should check with their doctor or pharmacist if they are not sure. The doctor will advise patients of the correct dose, which will depend on how bad their asthma is.
Increased risk of pneumonia in COPD patients	Pneumonia has been reported commonly in COPD patients (Pneumonia may affect up to 1 in 10 people).	Doctors should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. Patients should be advised about the risk factors for pneumonia by their doctors (current smoking, older age, low body mass index (BMI) and severe COPD).

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Risks in switching patients from oral corticosteroids to inhaled corticosteroids	The transfer of patients treated with oral corticosteroid to the inhaled corticosteroid and their subsequent management requires special care. During transfer from oral therapy to inhaled, patients might experience some symptoms as a result of this including a stuffy or runny nose, a lack of energy, depression, eczema (a type of skin rash) and joint and/or muscle pain.
Concurrent use of CYP3A4 inhibitors	CYP3A4 inhibitors such as medicines for the treatment of a fungal infection (e.g. ketoconazole, itraconozole),or some medicines for HIV (e.g. ritonavir, cobicistat) can increase systemic exposure to budesonide several fold. Patients are advised to tell their doctor or pharmacist if they are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Missing information

None

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) 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.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

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

Not applicable.