Part VI: Summary of the risk management plan

Summary of risk management plan for BUFANET (Budesonide)

This is a summary of the risk management plan (RMP) for BUFANET.

The RMP details important risks of BUFANET, how these risks can be minimised, and how more information will be obtained about BUFANET's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

BUFANET is authorised for the treatment of bronchial asthma and also in the treatment of very serious laryngitis subglottica (pseudocroup) in which hospitalisation is indicated.

It contains Budesonide as the active substance and it is given by pressurized inhalation, suspension.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of BUFANET together with measures to minimise such risks and the proposed studies for learning more about BUFANET risks, are outlined below.

Measures to minimise 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;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation measures*.

If important information that may affect the safe use of BUFANET is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of BUFANET are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of BUFANET. 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. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	• Pneumonia • Oropharyngeal candida infection • Use in acute episodes of asthma • Paradoxical bronchospasm • Systemic effects of inhaled corticoids • Impaired adrenal function • Growth retardation (in children and adolescents) • Use in patients with active and quiescent tuberculosis and in patients with fungal, viral or other infections of the airways • Interaction with CYP3A4 inhibitors
Important potential risks	• Use in patients with reduced liver function • Use in pregnancy • Use when breast-feeding
Missing information	• Safety in children aged under 6 months • Use of untested nebulizer systems

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

Pneumonia	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	There is an increased risk of Detection of early signs and pneumonia in patients with newly symptoms diagnosed COPD starting treatment with inhaled corticosteroids.
Risk minimisation measures	Routine risk minimisation measures.

Oropharyngeal candida infection	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	Oral candidiasis may occur during the therapy with inhaled corticosteroids. The Candida infection in the oropharynx is due drug deposition.
Risk minimisation measures	Patients should rinse their mouth out with water after inhaling to minimize the risk of oropharyngeal Candida infection.

Use in acute episodes of asthma	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	Patients should not use Budesonide for the rapid relief of acute episodes of asthma.
Risk minimisation measures	May be necessary to consult a physician in order to an increase in the patient regular therapy , e.g. higher doses of inhaled Budesonide or the addition of a long- acting beta agonist, or for a course of oral glucocorticosteroid.

Paradoxical bronchospasm	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	As with other inhalation therapy, paradoxical bronchospasm may occur in very rare cases, with an immediate increase in wheezing after dosing.
Risk minimisation measures	Routine risk minimisation measures

Systemic effects of inhaled corticoids	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	Patients (including children and adolescents) in therapy with inhaled corticosteroid, particularly at high doses and prescribed for long periods.
Risk minimisation measures	Routine risk minimisation measures

Impaired adrenal function	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	Patients who have required high dose emergency corticosteroid symptoms therapy or prolonged treatment at the highest recommended dose of inhaled corticosteroids.
Risk minimisation measures	Routine risk minimisation measures

Growth retardation (in children and adolescents)	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	Pediatric population may experience slowing growth
Risk minimisation measures	Growth should be monitored.

Use in patients with active and quiescent tuberculosis and in patients with fungal, viral or other infections of the airways	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	Special caution is necessary in patients with active or quiescent pulmonary tuberculosis and in patients with fungal or viral infections in the airways.
Risk minimisation measures	Routine risk minimisation measures

Interaction with CYP3A4 inhibitors	
Evidence for linking the risk to the medicine	Serious adverse reactions that may lead to a serious outcome
Risk factors and risk groups	Concomitant treatment with CYP3A4 inhibitors causes an increased risk of the systemic effects of corticosteroids.
Risk minimisation measures	The association should be avoided.

Use in patients with reduced liver function	
Risk minimisation measures	Routine risk minimisation measures

Use in pregnancy	
Risk minimisation measures	Routine risk minimisation measures

Use when breast-feeding	
Risk minimisation measures	Routine risk minimisation measures

Safety in children aged under 6 months	
Risk minimisation measures	Routine risk minimisation measures

Use of untested nebulizer systems	
Risk minimisation measures	Routine risk minimisation measures

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation for BUFANET

II.C.2 Other studies in post-authorisation development plan

There are no studies required for BUFANET.