SUMMARY OF RISK MANAGEMENT PLAN FOR *ALVESCO 80® OR 160® MICROGRAMS/ACTUATION, INHALED AEROSOL, SOLUTION* (CICLESONIDE)

This is a summary of the risk management plan (RMP) for **Alvesco 80® micrograms/actuation, Inhaled Aerosol, Solution** and **Alvesco 160® micrograms/actuation, Inhaled Aerosol, Solution** (herein after **Alvesco**). The RMP details important risks of **Alvesco** and how more information will be obtained about **Alvesco**'s risks and uncertainties (missing information).

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

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

I THE MEDICINE AND WHAT IT IS USED FOR

Alvesco is authorised for the treatment of asthma in adults and adolescents (12 years and older) (see SmPC for the full indication). It contains ciclesonide as the active substance and it is given by inhalation.

II RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERIZE THE RISKS

Important risks of **Alvesco**, together with measures to minimise such risks and the proposed studies for learning more about **Alvesco**'s 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of <invented name> is not yet available, it is listed under ‘missing information’ below.

II.A List of Important Risks and Missing Information

Important risks of **Alvesco** are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 **Alvesco**. 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);

Table II.1: Lists of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	Pregnant and breast-feeding women

II.B Summary of Important Risks Information

Missing information: Pregnant and breast-feeding women	
Risk minimisation measures	**Routine risk minimisation measures** SmPC section 4.6 Package Leaflet (PL) section 2 **Additional risk minimisation measures** No risk minimisation measures

II.C Post-Authorisation Development Plan

II.C.1 Studies Which Are Conditions of the Marketing Authorisation

Not applicable.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for **Alvesco**.