Part VI: Summary of the risk management plan

Summary of risk management plan for Salmeterol/Fluticasone Wellnex 50 microgram/100 microgram/dose inhalation powder, pre-dispensed; Salmeterol/Fluticasone Wellnex 50 microgram/250 microgram/dose inhalation powder, pre-dispensed; Salmeterol/Fluticasone Wellnex 50 microgram/500 microgram/dose inhalation powder, pre-dispensed (salmeterol xinafoate/fluticasone propionate)

This is a summary of the risk management plan (RMP) for Salmeterol/Fluticasone Wellnex 50 microgram/100 microgram/dose inhalation powder, pre-dispensed and Salmeterol/Fluticasone Wellnex 50 microgram/250 microgram/dose inhalation powder, pre-dispensed, Salmeterol/Fluticasone Wellnex 50 microgram/500 microgram/dose inhalation powder, pre-dispensed. The RMP details important risks of Salmeterol/Fluticasone Wellnex, how these risks can be minimised, and how more information will be obtained about Salmeterol/Fluticasone Wellnex's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Salmeterol/Fluticasone Wellnex is authorised for asthma (see SmPC for the full indication). It contains salmeterol xinafoate and fluticasone propionate as the active substances and it is given by inhalation.

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

Important risks of Salmeterol/Fluticasone Wellnex, together with measures to minimise such risks and the proposed studies for learning more about Salmeterol/Fluticasone Wellnex'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*.

II.A List of important risks and missing information

Important risks of Salmeterol/Fluticasone Wellnex are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by inhalation. 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 Salmeterol/Fluticasone Wellnex. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

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

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

Not applicable

Summary of risk management plan for Neuair Airmaster 50 microgram/100 microgram/ dose inhalation powder, pre-dispensed; Neuair Airmaster 50 microgram/250 microgram/ dose inhalation powder, pre-dispensed; Neuair Airmaster 50 microgram/500 microgram/ dose inhalation powder, pre-dispensed (salmeterol xinafoate/fluticasone propionate)

This is a summary of the risk management plan (RMP) for Neuair Airmaster 50 microgram/100 microgram/ dose inhalation powder, pre-dispensed; Neuair Airmaster 50 microgram/250 microgram/ dose inhalation powder, pre-dispensed; Neuair Airmaster 50 microgram/500 microgram/ dose inhalation powder, pre-dispensed. The RMP details important risks of Neuair Airmaster, how these risks can be minimised, and how more information will be obtained about Neuair Airmaster's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Neuair Airmaster is authorised for asthma (see SmPC for the full indication). It contains salmeterol xinafoate and fluticasone propionate as the active substances and it is given by inhalation.

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

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

II.A List of important risks and missing information

Important risks of Neuair Airmaster are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by inhalation. 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 Neuair Airmaster. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

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

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

Not applicable