EKLIRA GENUAIR

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SWISS SUMMARY OF RISK MANAGEMENT PLAN

Version Number: Summary related to RMP version 10.1

Based on European Union RMP Version: 10.1

Marketing Authorization Holder: Azurity GmbH

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The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risk as well as to prevent or minimize them.

The RMP summary of Eklira Genuair is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the "Arzneimittelinformation / Information sur le médicament" approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Eklira Genuair in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and authorized by Swissmedic. Azurity GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of Eklira Genuair.

1 SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF THE RISK MANAGEMENT PLAN FOR EKLIRA GENUAIR

This is a summary of the risk management plan (RMP) for Eklira Genuair. The RMP details important risks of Eklira Genuair and how more information will be obtained about Eklira Genuair's risks and uncertainties (missing information).

Eklira Genuair's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Eklira Genuair should be used.

This summary of the RMP for Eklira Genuair should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Eklira Genuair is authorised for chronic obstructive pulmonary disease (COPD) (see SmPC for the full indication). It contains aclidinium bromide as the active substance and it is given by inhalation.

Further information about the evaluation of Eklira Genuair's benefits can be found in Eklira Genuair's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/eklira-genuair.

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

Important risks of Eklira Genuair, together with measures to minimise such risks and the proposed studies for learning more about Eklira Genuair'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 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 periodic safety update report (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 Eklira Genuair 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 Eklira Genuair. 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 risk	None
Important potential risk	None
Missing information	None

II.B Summary of important risks

There are no important identified risks, important potential risks or missing information for Eklira Genuair.

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 obligations of Eklira Genuair.

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

There are no studies required for Eklira Genuair.