ALECENSA®
150 mg, Hartkapseln
Zul.-Nr. 65‘970

Public Risk Management Plan (RMP) Summary

Document Version: 4.0
Document Date: 21.06.2024
Based on EU RMP version 4.0 (06.09.2023)

Roche Pharma (Schweiz) AG
www.roche.ch/pharma, 4058 Basel

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 risks as well as to prevent or minimize them. The RMP summary of Alecensa® 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“ 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 Alecensa® in Switzerland is the „Arzneimittelinformation“ (see www.swissmedicinfo.ch) approved and authorized by Swissmedic.

Roche Pharma (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the here published RMP summary of Alecensa®.

Roche Pharma (Schweiz) AG
Grenzacherstrasse 124
CH-4058 Basel
pharma.schweiz@roche.com
www.roche.ch/pharma
Tel. +41 61 715 41 11

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR ALECTINIB (ALECENSA)

This is a summary of the risk management plan (RMP) for Alecensa. The RMP details important risks of Alecensa, how these risks can be minimized, and how more information will be obtained about Alecensa risks and uncertainties (missing information).

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

This summary of the RMP for Alecensa 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 Alecensa RMP.

I. THE MEDICINE AND WHAT IT IS USED FOR

Adjuvant Treatment of Resected Non-Small Cell Lung Cancer

Alecensa as monotherapy is indicated as adjuvant treatment following tumor resection for adult patients with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC).

Treatment of Advanced Non-Small Cell Lung Cancer

Alecensa is authorized for the treatment (as monotherapy) of adult patients with ALK-positive advanced NSCLC previously treated with crizotinib. Additionally, Alecensa as monotherapy is indicated for the first line treatment of adult patients with ALK-positive advanced NSCLC.

It contains alectinib as the active substance and it is given by oral administration.

Further information about the evaluation of Alecensa's benefits can be found in Alecensa's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

Roche Pharma (Schweiz) AG Grenzacherstrasse 124 CH-4058 Basel pharma.schweiz@roche.com www.roche.ch/pharma Tel. +41 61 715 41 11

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

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

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, 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 Alecensa are risks that need special risk management activities to further investigate or minimize 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 Alecensa. 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 longterm use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

Roche Pharma (Schweiz) AG Grenzacherstrasse 124 CH-4058 Basel pharma.schweiz@roche.com www.roche.ch/pharma Tel. +41 61 715 41 11

II.B SUMMARY OF IMPORTANT RISKS

There are no important risks for alectinib.

II.C POST-AUTHORISATION DEVELOPMENT PLAN

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

There are no studies which are conditions of the marketing authorization.

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

There are no studies planned for alectinib.

Roche Pharma (Schweiz) AG Grenzacherstrasse 124 CH-4058 Basel pharma.schweiz@roche.com www.roche.ch/pharma Tel. +41 61 715 41 11