Swiss Summary of the Risk Management Plan (RMP) for Alunbrig®, Filmtabletten

Marketing Autorisation Holder : Takeda Pharma AG
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Based on EU RMP version 5.3

Disclaimer:

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 Alunbrig®, Filmtabletten 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 medicament" 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 Alunbrig®, Filmtabletten in Switzerland is the "Arzneimittelinformation / Information sur le medicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Takeda Pharma AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Alunbrig®, Filmtabletten.

The medicine and what it is used for

Alunbrig is authorized for the treatment of adult patients with ALK+ advanced NSCLC previously treated with crizotinib and as monotherapy for the treatment of adult patients with ALK+ advanced NSCLC previously not treated with an ALK inhibitor (see SmPC for the full indication). It contains brigatinib as the active substance and it is given by mouth.

Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Alunbrig, together with measures to minimize such risks and the proposed studies for learning more about Alunbrig's 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 PL and SmPC addressed to patients and HCPs.
- 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 (eg, with or without prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

In the case of Alunbrig, these measures are supplemented with additional risk minimization measures mentioned under relevant important risks, below.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, including Periodic Safety Update Report 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 Alunbrig is not yet available, it is listed under 'missing information' below.

List of Important Risks and Missing Information

Important risks of Alunbrig 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 Alunbrig. 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 (eg, on the long-term use of the medicine);

List of Important Risks and Missing Information

Important identified risks	Pulmonary toxicity (including EOPE and later-onset pneumonitis)
Missing information	None

Abbreviation: EOPE, early-onset pulmonary event.

Summary of Important Risks

Important Identified Risk: Pulmonary Toxicity (including EOPE and later-onset pneumonitis)

Evidence for linking the risk to the medicine	On the basis of clinical study results, there is sufficient evidence demonstrating potential causal association.
Risk factors and risk groups	Increasing age (>60 years) and shorter interval between last dose of crizotinib and first dose of brigatinib (<7-day interval) are considered to be specific risk factors for pulmonary events.
Risk minimization measures	**Routine risk minimization measures:** SmPC Sections: 4.2 Posology and method of administration (ILD/pneumonitis) 4.4 Special warnings and precautions for use (Pulmonary adverse reactions) 4.8 Undesirable effects (Pulmonary adverse reactions) **Additional risk minimization measures:** PAC
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** Brigatinib PASS

Missing Information: None

Postauthorization Development Plan

Studies Which Are Conditions of the MA

AP26113-13-301
Purpose of the study:

- To further characterize the efficacy and safety of brigatinib in the treatment of patients with ALK-positive NSCLC.

Other Studies in Postauthorization Development Plan

Brigatinib PASS

Purpose of the study:

- To describe the occurrence and risk factors of EOPE in patients with ALK+ NSCLC receiving brigatinib.
- To assess the receipt and use of the PAC in patients treated with brigatinib.