Fasenra®

30 mg, solution for injection

Summary of the Risk Management Plan (RMP) for Fasenra®(Benralizumab)

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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 risks as well as to prevent or minimise them.

The RMP summary of Fasenra® 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 Fasenra® in Switzerland is the "Arzneimittelinformation/ Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. AstraZeneca AG is fully responsible for the accuracy and correctness of the content of the published summary RMP of Fasenra®.

Summary of the risk management plan (RMP) for Fasenra® (Benralizumab)

This is a summary of the RMP for FASENRA®. The RMP details important risks of FASENRA®, how these risks can be minimised, and how more information will be obtained about FASENRA®'s risks and uncertainties (missing information).

FASENRA®'s prescribing information and its package leaflet give essential information to healthcare professionals and patients on how FASENRA® should be used.

I.1 THE MEDICINE AND WHAT IT IS USED FOR

FASENRA® is authorised for an add-on maintenance treatment for severe asthma with an eosinophilic phenotype in adult patients and is authorised for the treatment of adult patients with EGPA. It contains benralizumab as the active substance. For the treatment of severe asthma it is given by SC injection Q4W for the first 3 doses, and then Q8W thereafter. For the treatment of EGPA it is given by SC injection Q4W.

I.2 RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of FASENRA®, together with measures to minimise such risks and the proposed studies for learning more about FASENRA®'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 prescribing information 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 Benefit Risk Evaluation Report (PBRER) 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 FASENRA® is not yet available, it is listed under 'missing information' below.

I.2.1 List of Important Risks and Missing Information

Important risks of FASENRA® 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 FASENRA®. 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.

Table 1 List of Important Risks and Missing Information

Important identified risks	None
Important potential risks	Malignancies
Missing Information	Use in pregnant and lactating women

I.2.2 Summary of Important Risks

Table 2 Important Potential Risk: Malignancy

Evidence for linking the risk to the medicine	Since benralizumab targets eosinophils for destruction, it is important to understand what physiological impact eosinophil depletion may have in relation to malignancy risk. While eosinophils have been found in association with solid tumours, especially tumours of epithelial origin (breast and colon), the role eosinophils may have in tumour growth, if any, remains unclear. While some clinical studies have suggested the presence of eosinophils may be a positive prognostic indicator of cancer patient survival, a definitive link has not yet been established. Malignancies have been reported in the completed studies of benralizumab. The incidence of malignancies reported was low and similar across treatment groups.
Risk factors and risk groups	In studies examining broad populations of asthma, no significant associations between asthma and overall cancer incidence have been found. There is some evidence to suggest that patients with asthma may have an increased risk of developing lung cancer. The data are thus conflicting, and further research is needed to elucidate this hypothesis. In a multicentre study EGPA patients had a two-fold risk of overall malignancy compared to the general population. There is a greater paucity of data concerning the effect that biologics may have on malignancies when used to treat asthma. While eosinophils have been found in association with solid tumours, especially tumours of epithelial origin (breast and colon), the role eosinophils may have in tumour growth, if any, remains unclear. While some clinical studies have suggested the presence of eosinophils may be a positive prognostic indicator of cancer patient survival, a definitive link has not yet been established.

Risk minimisation measures	No risk minimisation measures
Additional pharmacovigilance activities	D3250R00042 (Malignancy Post Authorization Safety Study)

Table 3 Missing Information: Use in Pregnancy and Lactation

Risk minimisation measures	Routine risk minimisation measures: SmPC Section "Pregnancy, lactation"
Additional pharmacovigilance activities	None

I.2.3 Post-authorisation Development Plan

I.2.3.1 Studies which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of FASENRA®.

I.2.3.2 Other Studies in Post-authorisation Development Plan

Malignancy Post Authorisation Safety Study (D3250R00042)

Study short name and title: Descriptive Study of The Incidence of Malignancy in Severe Asthma Patients Receiving Benralizumab or Other Therapies, a Post Authorization Safety Study.

Purpose of the study: The primary objective of this study is to assess the incidence of malignancies in severe asthma patients receiving benralizumab compared with those receiving non-benralizumab biologics, and those not receiving biologics. The secondary objective is to describe the clinical characteristics of the new malignancy cases that develop in severe asthma patients and relevant subgroups.