Imfinzi®

50 mg/ml, Concentrate for solution for infusion

Summary of the Risk Management Plan (RMP) for Imfinzi® (durvalumab)

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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 Imfinzi® 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 Imfinzi® 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 Imfinzi®.

1. THE MEDICINE AND WHAT IT IS USED FOR

IMFINZI is authorised

- As monotherapy for the treatment of locally advanced, unresectable NSCLC in patients whose disease has not progressed following platinum-based chemoradiation therapy
- In combination with etoposide and either carboplatin or cisplatin for the first line treatment of patients with ES-SCLC
- In combination with chemotherapy for the treatment of adults with locally advanced or metastatic biliary tract cancer.

IMFINZI contains durvalumab as the active substance and is administered as an intravenous infusion.

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

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

Measures to minimise the risks identified for medicinal products can be as follows:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and product 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 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 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 assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

2.1 List of important risks and missing information

Important risks of IMFINZI 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 IMFINZI. 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).

There are no safety concerns for IMFIMZI.

2.2 Summary of important risks

There are no safety concerns for IMFINZI.

3. POST-AUTHORISATION DEVELOPMENT PLAN

3.1 Studies which are conditions of the marketing authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation for IMFINZI.

3.2 Other studies in post-authorisation development plan

There are no studies required for IMFINZI.