Inluriyo®

(imlunestrant)

200 mg

film-coated tablet

Summary of Risk Management Plan (RMP)

Eli Lilly (Suisse) SA

Summary of the Risk Management plan (RMP) for Inluriyo (imlunestrant)

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 Inluriyo 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 Inluriyo in Switzerland is the „Arzneimittelinformation/ Information sur le médicament“ (see www.swissmedicinfo.ch) approved and authorized by Swissmedic.

Eli Lilly is fully responsible for the accuracy and correctness of the content of this published summary RMP of Inluriyo.

- ***I - The Medicine and What It is Used for***

Inluriyo is authorised for adults with ER-positive, HER2-negative, and ESR1-mutated locally advanced or metastatic BC in patients previously treated with endocrine therapy (see SmPC for the full indication). It contains imlunestrant as the active substance and it is given orally.

Further information about the evaluation of Inluriyo’s benefits can be found in Inluriyo’s European Public Assessment Report, including in its plain-language summary, available on the EMA website, under the medicine’s webpage.

- ***II - Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks***

Important risks of Inluriyo, together with measures to minimise such risks and the proposed studies for learning more about Inluriyo’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 SmPC 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.

- ***II.A List of Important Risks and Missing Information***

Important risks of Inluriyo 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 Inluriyo. 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 risks	None
Important potential risks	Gastrointestinal bleeding
Missing information	None

- ***II.B Summary of Important Risks***

Important potential risk 1: gastrointestinal bleeding	
Evidence for linking the risk to the medicine	While GI bleeding occurs infrequently in this population, recent observations warrant the consideration as a potential risk. Overall, the strength of the available relevant evidence is limited to a few case reports. GI bleeding has not been associated with oestrogen-targeted therapies for breast cancer. Only a few cases of GI bleeding have been reported in case series and clinical trials, including fulvestrant in the CONFIRM (NCT00099437) and MONALEESA-3 trials (NCT02422615) and anastrozole in the FALCON trial (NCT01602380). A longitudinal study that planned to assess haemorrhagic complications of liver metastases in patients with advanced cancer demonstrated an increased risk of GI bleeding. However, there are substantial differences between the population of this study, which included patients referred for palliative care and did not study any patients with breast cancer, and the population enrolled in EMBER-3 (Mercadante et al. 2000). For imlunestrant, a causal association with GI bleeding has not been established; a low number of GI bleeding events have been reported in the clinical development programme, including 2 events with fatal outcomes.
Risk factors and risk groups	Due to the low number of cases, it is not possible to identify specific risk factors or patient subgroups from the imlunestrant clinical data. In general, upper GI bleeding has been more frequently reported in patients with liver metastases, peptic ulcer disease, or those receiving medications such as SSRIs, non-steroidal anti-inflammatory drugs, and corticosteroids. Additional risk factors include older age, low body weight, and chronic kidney disease (Mercadante et al. 2000; Dalton et al. 2003; EMEA 2005; Wong et al. 2013; Narum et al. 2014; Bosch et al. 2025).
Risk minimisation measures	**Routine risk minimisation measures:** Not applicable. **Additional risk minimisation measures:** Not applicable.
Additional pharmacovigilance activities	**Additional pharmacovigilance activities:** None. See Section II.C of this summary for an overview of the post-authorisation development plan.

- ***II.C Post-authorisation Development Plan***

- **II.C.1 Studies that are Conditions of the Marketing Authorisation**

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

- **II.C.2 Other Studies in Post-authorisation Development Plan**

There are no studies required for Inluriyo.