Swiss Public Summary of the Risk Management Plan (RMP)

for

Zydelig®, Film-coated tablets

(idelalisib)
100 mg & 150 mg

Version 3.0 (August 2023)
Based on EU RMP version 7.0 (April 2023)

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1. SUMMARY OF RISK MANAGEMENT PLAN FOR ZYDELIG® (IDELALISIB)

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 Zydelig 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 Zydelig in Switzerland is the „Arzneimittelinformation / Information sur le médicament“ (see www.swissmedic.ch) approved authorized by Swissmedic. Gilead Sciences Switzerland Sàrl is fully responsible for the accuracy and correctness of the content of the here published summary RMP of Zydelig.

I. The Medicine and What is it Used for

Zydelig is authorized for the treatment of certain patients with chronic lymphocytic leukemia (CLL) or follicular lymphoma (FL) (see SmPC for the full indication). It contains idelalisib as the active substance and it is given by mouth.

Further information about the evaluation of Zydelig’s benefits can be found in Zydelig’s EPAR, including in its plain-language summary, available on the EMA website, under the medicine’s webpage:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/003843/human_med_001803.jsp&mid=WC0b01ac058001d124

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterize the Risks

Important risks of Zydelig, together with measures to minimize such risks and the proposed studies for learning more about Zydelig’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 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 public (e.g. with or without prescription) can help to minimizes its risks.

Together, these measures constitute routine risk minimization measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed including PSUR 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 Zydelig is not yet available, it is listed under 'missing information' below.

II.A. List of important risks and missing information

Important risks of Zydelig are risks that need special risk management activities to further investigate or minimise 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 Zydelig. 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);

Table Part VI.1. List of Important Risks and Missing Information

Important Identified Risks	None
Important Potential Risks	None
Missing Information	None

II.B. Summary of Important Risks

Zydelig has been assigned the legal status of a medicine subject to medical prescription in the European Union (EU), whereby therapy should be initiated by a doctor experienced in the management of anticancer therapies (as described in section 4.2 of the SmPC).

There are no important risks or missing information for Zydelig.

II.C. Post-authorization Development Plan

II.C.1. Studies which are Conditions of the Marketing Authorization

None

II.C.2. Other Studies in Post-Authorization Development Plan

None