# Swiss Public Summary of the Risk Management Plan (RMP)

# for

**LYVDELZI®, Hard Capsules**

(Seladelpar)

Version 1.0 (December 2025)
Based on EU RMP version 1.0 (December 2024)

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# SUMMARY OF RISK MANAGEMENT PLAN FOR LYVDELZI® (SELADELPAR)

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 minimize them.

The RMP summary of Lyvdelzi® (seladelpar) 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 Lyvdelzi® in Switzerland is the „Arzneimittelinformation / Information sur le médicament" (see www.swissmedicinfo.ch) approved and 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 Lyvdelzi®.

## I. The Medicine and What is it Used For

Seladelpar Gilead is authorised for primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA alone, or as monotherapy in adults unable to tolerate UDCA (see SmPC for the full indication). It contains seladelpar lysine as the active substance and it is given by oral route of administration.

Further information about the evaluation of Seladelpar Gilead's benefits can be found in Seladelpar Gilead's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage <link to the EPAR summary landing page>.

## II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Seladelpar Gilead, together with measures to minimise such risks and the proposed studies for learning more about Seladelpar Gilead'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.

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

### *VI.A List of important risks and missing information*

Important risks of Seladelpar Gilead 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 Seladelpar Gilead. 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 | Hepatotoxicity |
| Missing information | Use in Pregnancy |
| | Long term safety |
| | Use in PBC patients with moderate (Child Pugh B) hepatic impairment |

### *VI.B Summary of important risks*

The safety information in the proposed Product Information is aligned to the reference medicinal product.

| **Important Identified Risk: None** |
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| **Important Potential Risk: Hepatotoxicity** | |
| Evidence for linking the risk to the medicine | **Non-clinical findings:** Minimal, reversible, hepatocellular necrosis was observed in male rats receiving the highest dose of 50 mg/kg/day in the 26-week study and male monkeys receiving ≥5 mg/kg/day for 52 weeks.<br><br>**Clinical findings:**<br>Seladelpar has been associated with transient dose dependent increases in serum transaminases (AST and ALT) levels greater than 3 times upper limit of normal (ULN) in subjects with PBC receiving doses of 50 and 200 mg/day (5- and 20-times the recommended 10 mg/day dose). Transaminase levels returned to pretreatment levels upon treatment discontinuation. |
| Risk factors and risk groups | The potential for drug-induced liver injury as reflected in increases in liver enzymes, including transaminases, may vary according to the stage of the underlying disease. Decreased hepatic function can lead to higher drug exposure increasing the risk of drug injury. Existing injury to the parenchyma and vascular system can increase the risk of injury. |
| Risk minimisation measures | **Routine risk minimization measures:**<br><br>SmPC section 4.4<br>PL section 2<br>Prescription-only medicine<br><br>**Additional risk minimization measures:**<br><br>None |
| Additional pharmacovigilance activities | Study CB8025-21838<br><br>Study CB8025-31731-RE |
| **Missing Information: Use in Pregnancy** | |
| Risk minimisation measures | **Routine risk minimization measures:**<br><br>SmPC section 4.6<br>SmPC section 5.3<br>PL section 2<br>Prescription-only medicine<br><br>**Additional risk minimization measures:**<br><br>None |
| **Missing Information: Long term safety** | |
| Risk minimisation measures | **Routine risk minimisation measures:** |

| | |
|---|---|
| | SmPC none<br>PL none<br>Prescription-only medicine<br><br>**Additional risk minimisation measures:**<br><br>None |
| Additional pharmacovigilance activities | Study CB8025-31731-RE |
| **Missing Information: Use in PBC patients with moderate (Child Pugh B) hepatic impairment** | |
| Risk minimisation measures | **Routine risk minimisation measures:**<br><br>SmPC Section 4.2<br>PL none<br>Prescription-only medicine<br><br>**Additional risk minimisation measures:**<br><br>None |
| Additional pharmacovigilance activities | Study CB8025-21838<br>Study CB8025-31731-RE |

## *VI.C Post-authorisation development plan*

### VI.C.1 Studies which are conditions of the marketing authorisation

The following studies are conditions of the marketing authorization:

**Study short name: CB8025-41837 (AFFIRM)**

Purpose of the study: A randomised, double-blind, placebo-controlled, study to evaluate the effect of seladelpar on clinical outcomes in patients with compensated cirrhosis and PBC.

### VI.C.2 Other studies in post-authorisation development plan

**Study short name: CB8025-21838**

Purpose of the study: To evaluate the effect of hepatic impairment on the pharmacokinetics of seladelpar: An open-label study following oral dosing of seladelpar to subjects with PBC and HI.

**Study short name: CB8025-31731-RE (ASSURE)**

Purpose of the study: to evaluate the long-term safety and tolerability, long-term efficacy, and effect of oral seladelpar on patient-reported outcomes in subjects with PBC.

# SUMMARY OF SWITZERLAND SPECIFIC ANNEX TO EU RISK MANAGEMENT PLAN FOR LYVDELZI® (SELADELPAR)

There is no Switzerland Specific Annex required.

This summary was last updated in December 2025.