ITOVEBI®
3 mg, 9 mg; Filmtabletten
Zul.-Nr. 69‘792

Public Risk Management Plan (RMP) Summary

Document Version: 1.0
Document Date: 06.03.2025
Based on Core RMP version 1.0 (27.03.2024)

Roche Pharma (Schweiz) AG
www.roche.ch/pharma, 4058 Basel

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 Itovebi® 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“ 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 Itovebi® in Switzerland is the „Arzneimittelinformation“ (see www.swissmedicinfo.ch) approved and authorized by Swissmedic.

Roche Pharma (Schweiz) AG is fully responsible for the accuracy and correctness of the content of the here published RMP summary of Itovebi®.

Roche Pharma (Schweiz) AG
Grenzacherstrasse 124
CH-4058 Basel
pharma.schweiz@roche.com
www.roche.ch/pharma
Tel. +41 61 715 41 11

11.3 SUMMARY OF RISK-MINIMIZATION MEASURES

Table 18 Summary Table of Pharmacovigilance Activities and Risk-Minimization Activities by Safety Concern

Safety concern	Risk-minimization measures	Pharmacovigilance activities
Hyperglycemia	Routine risk-minimization measures: CDS section 2.2.5, 2.4.1, and 2.6.1 Dose modification and management advice for hyperglycemia is included in CDS section 2.2.5. Recommendations on monitoring and optimization of blood glucose levels for the management of hyperglycemia is included in CDS section 2.4.1. Other routine risk-minimization measures beyond the Product Information: Pack size Medicine's legal status: Inavolisib is a prescription only medicine Additional risk-minimization measures: Patient Card	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: No activities beyond routine PSUR/PBRER reporting Additional pharmacovigilance activities: None
Safety in patients with moderate to severe renal impairment	Routine risk-minimization measures: CDS section 2.2.6.3, 2.5.6, and 3.2.5 Information pertaining to dose instructions in patients with renal impairment is included in CDS section 2.2.6.3 and Section 2.5.6.	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: No activities beyond routine PSUR/PBRER reporting Additional pharmacovigilance

Roche Pharma (Schweiz) AG Grenzacherstrasse 124 CH-4058 Basel pharma.schweiz@roche.com www.roche.ch/pharma Tel. +41 61 715 41 11

	Other routine risk-minimization measures beyond the Product Information: Pack size Medicine's legal status: Inavolisib is a prescription only medicine No additional risk-minimization measures	activities: Study GP44944
Safety in patients with Type 2 diabetes mellitus	Routine risk-minimization measures: CDS section 2.4.1 Information pertaining to the use of inavolisib in patients with Type 2 diabetes is included in CDS section 2.4.1. Other routine risk-minimization measures beyond the Product Information: Pack size Medicine's legal status: Inavolisib is a prescription only medicine No additional risk-minimization measures	Routine pharmacovigilance activities beyond adverse reactions reporting and signal detection: No activities beyond routine PSUR/PBRER reporting Additional pharmacovigilance activities: Planned Study to evaluate inavolisib-associated hyperglycemia in Type 2 diabetic patients

CDS = Core Data Sheet; PBRER = Periodic Benefit-Risk Evaluation Report, PSUR = Periodic Safety Update Report.

Roche Pharma (Schweiz) AG Grenzacherstrasse 124 CH-4058 Basel pharma.schweiz@roche.com www.roche.ch/pharma Tel. +41 61 715 41 11