Filspari

INN: Sparsentan

Swiss Summary to the Risk Management Plan

Version number of RMP Summary: 1.0

Based on EU RMP Version 0.6

Marketing Authorisation Holder: Vifor (International) Inc.

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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 Filspari 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 Filspari in Switzerland is the "Arzneimittelinformation / Information sur le médicament" (see www.swissmedic.ch) approved and authorized by Swissmedic. Vifor (International) Inc is fully responsible for the accuracy and correctness of the content of the published summary RMP of Filspari.

Summary of Risk Management Plan for Filspari (Sparsentan)

The medicine and what it is used for

Filspari is indicated for the treatment of adults with primary immunoglobulin A nephropathy (IgAN) with a urine protein excretion ≥1.0 g/day (or urine protein-to-creatinine ratio ≥0.75 g/g). It contains sparsentan as the active substance and it is given as 200 mg and 400 mg film-coated tablets.

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

Important risks of Filspari, together with measures to minimise such risks and the proposed studies for learning more about Filspari'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 Summary of Product Characteristics 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 the case of Filspari, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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.

If important information that may affect the safe use of Filspari is not yet available, it is listed under ‘missing information’ below.

List of Important Risks and Missing Information

Important risks of Filspari 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 Filspari. 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	Drug-induced liver injury
	Teratogenicity
Missing Information	Use in patients with heart failure
	Use in patients with severe hepatic impairment
	Use during breastfeeding
	Use in patients after renal transplantation

Summary of important risks

Important Potential Risk: Drug-induced liver injury	
Evidence for linking the risk to the medicine	Medicines with the similar mode of action (ERAs and ARBs) are associated with an increased risk of drug-induced liver injury. Pooled data from subjects treated in the sparsentan IgAN and FSGS clinical development programme. Nonclinical data from toxicology studies.
Risk factors and risk groups	Common risk factors for hepatotoxicity include: • Older age • Female gender • Underlying liver diseases (e.g., hepatitis) • Other comorbidities such as AIDS • Genetic predisposition involving CYP450, HLA alleles and other drug-processing enzymes • Chronic alcohol consumption • Concomitant use of hepatotoxic medications
Risk minimisation measures	Routine risk minimisation measures: • SmPC Section 4.4 • SmPC Section 4.8 • PL Section 2 • PL Section 4 • Legal status: subject to medical prescription Additional risk minimisation measures: Patient Card

Important Potential Risk: Teratogenicity	
Evidence for linking the risk to the medicine	Nonclinical studies in which birth defects were observed, demonstrating the potential risk of teratogenicity for sparsentan. Medicines with a similar mode of action are associated with an increased risk of foetal harm during pregnancy.
Risk factors and risk groups	All women of childbearing potential.
Risk minimisation measures	Routine risk minimisation measures: • SmPC Section 4.3 • SmPC Section 4.4 • SmPC Section 4.6 • SmPC Section 5.3 • PL Section 2 • Legal status: restricted medical prescription Additional risk minimisation measures: Patient Card

Missing Information: Use in patients with heart failure	
Risk minimisation measures	Routine risk minimisation measures • SmPC Section 4.4 • Legal status: restricted medical prescription Additional risk minimisation measures: None

Missing Information: Use in patients with severe hepatic impairment	
Risk minimisation measures	Routine risk minimisation measures • SmPC Section 4.2 • SmPC Section 5.2 • Legal status: restricted medical prescription Additional risk minimisation measures: None

Missing Information: Use during breastfeeding	
Risk minimisation measures	Routine risk minimisation measures • SmPC Section 4.6 • PL Section 2 • Legal status: restricted medical prescription Additional risk minimisation measures: None

Missing Information: Use in patients after renal transplantation	
Risk minimisation measures	Routine risk minimisation measures • SmPC Section 4.2 • Legal status: subject to medical prescription Additional risk minimisation measures: None

Notes: AIDS=Acquired immunodeficiency syndrome; ARB=Angiotensin receptor blocker; ERA=Endothelin receptor antagonist; FSGS=Focal segmental glomerulosclerosis; HLA=human leukocyte antigen; IgAN=Immunoglobulin A nephropathy; PL=Package Leaflet; SmPC=Summary of Product Characteristics.

Post-authorisation Development Plan

Studies Which are Conditions of the Marketing Authorisation

The following study is a condition of the conditional marketing authorization:

Study 021IGAN17001 (PROTECT)

Purpose of the study: To confirm the long-term efficacy and safety of sparsentan for the treatment of primary immunoglobulin A nephropathy (IgAN) in adults, and in order to specifically assess the maintenance of the long-term efficacy and safety.

Other Studies in Post-authorisation Development Plan

There are no studies required for Filspari.

Summary of changes to the Swiss RMP Summary

Version	Date	Change History	Comment
01	06 Dec 2024	Initial document	Initial document based on EU RMP Version 0.6 dated 22 Feb 2024