swissmedic

Summary report on authorisation dated 31 January 2025

Filspari® (active substance: sparsentan)

Temporary authorisation in Switzerland: 14 October 2024

Film-coated tablet for the treatment of primary immunglobulin A nephropathy (IgAN) in adults

About the medicinal product

Filspari contains the active substance sparsentan.

Filspari is used to treat primary immunglobulin A nephropathy (IgAN) in adults with an excretion of protein in the urine of > 1.0 g/day or a protein-creatinine ratio in the urine of ≥ 0.75 g/g.

Primary IgA nephropathy (IgAN) is a disease of the kidneys in which the body's defence system (immune system) produces faulty immunglobulin A (IgA) antibodies. These antibodies are stored in the small blood vessels in the kidneys known as glomeruli, which are responsible for filtering the blood. However, they are damaged by the deposits, resulting in blood and protein leaking into the urine. Since IgAN is a rare and life-threatening disease, the medicinal product Filspari has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Filspari has been authorised by Swissmedic under Article 13 of the Therapeutic Products Act (TPA). This means that the medicinal product is already authorised in at least 1 other country with comparable medicinal product control.

In this case, Swissmedic takes into consideration the results of checks carried out by foreign regulatory agencies, provided certain requirements are fulfilled. These involve checks on the quality, efficacy, and safety of the medicinal product, and the extent to which the results can be accepted for Switzerland. The consideration of the results of foreign authorisation procedures is intended to help ensure that medicines that are already authorised abroad can be made available to patients in Switzerland as quickly as possible.

In deciding whether to authorise Filspari in Switzerland, Swissmedic accepted the assessment and approval decision of the European Medicines Agency (EMA) and has only conducted a limited scientific review.
Accordingly, in the SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation, Swissmedic refers to the Assessment Report issued by the reference authority: EMA Procedure Number EMEA/H/C/005783/0000 www.ema.europa.eu.

The medicinal product Filspari has been authorised temporarily in Switzerland (in ac-

cordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation. The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an authorisation without special conditions in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Filspari®

Information for patients (package leaflet): Information for patients Filspari®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.