swissmedic

Summary report on authorisation dated 5 November 2025

PulmoProDiff® (active substances: carbon monoxide, helium)

Authorisation in Switzerland: 17 March 2025

Medicinal gas for diagnostic testing of lung function

About the medicinal product

PulmoProDiff is a medicinal gas used for diagnostic purposes and contains carbon monoxide and helium as active substances.

PulmoProDiff is used for diagnostic testing of lung function (determination of diffusion capacity/transfer factor as the main parameter and determination of lung volume as an additional parameter). These tests are important in assessing lung performance.

PulmoProDiff may be used in patients of any age, provided that they are capable of performing the test.

PulmoProDiff was authorised under Art. 14 para. 1 let. a^{bis} of the Therapeutic Products Act (TPA). The TPA enables certain categories of medicines to be authorised according to a simplified procedure, provided this is compatible with the quality, safety, and efficacy requirements, and there is no conflict with Swiss interests or international obligations.

The authorisation of PulmoProDiff is based on the medicinal product ProMED pul-g He/CO 18% (V/V) / 0.25% (V/V), which contains the same active substances and has been authorised in Germany for more than 10 years for a comparable indication, dosage, and use.

Swissmedic assessed the quality data on the active substance and finished medicinal product but did not conduct its own comprehensive scientific review for other aspects. Efficacy and safety were only reviewed in summarised form.

The requirements for issuing a comprehensive SwissPAR (Swiss Public Assessment Report) and the resulting Summary report on authorisation have therefore not been met. Swissmedic refers to the authorisation of the foreign comparator medicinal product.

Further information on simplified authorisation according to Art. 14 para. 1 let. a^{bis} TPA can be found in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

Further information on the medicinal product

At the time of publication of the Summary report on authorisation for PulmoProDiff, the Information for healthcare professionals was not yet available. As soon as the medicinal product becomes available in Switzerland, the Information for healthcare professionals will be made available on the following website: www.swissmedicinfo.ch.
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.