

Public Summary SwissPAR dated 15 June 2022

Colibiogen Oral[®] (active substance: cell-free solution of lysed *Escherichia coli* culture, strain Laves)

First authorisation in Switzerland: 7 April 2022

Medicinal product (oral solution) for supportive, symptomatic treatment of irritable bowel syndrome in adults

Information on authorisation

The active substance in the medicinal product Colibiogen Oral is a bacterial lysate of *Escherichia coli*, strain Laves.

It is an oral solution that is taken with some liquid.

Colibiogen Oral has been authorised in Switzerland for supportive, symptomatic treatment of irritable bowel syndrome in adults.

Colibiogen Oral was approved under a simplified authorisation procedure according to Art. 14 para. 1 let. a^{quater} 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 Colibiogen Oral is based on the medicinal product Colibiogen

Oral, which contains the same active substance and has been authorised for a comparable indication, dosage and use in Canton Appenzell Ausserrhoden for more than 15 years.

Swissmedic assessed the quality data on the active substance and finished 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 complete SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR have therefore not been met.

Further information on simplified authorisation according to Art. 14 TPA can be found in the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

Further information on the medicinal product

Depending on the dispensing category of the medicinal product, Information for healthcare professionals may not be required. At the time of publication of the Public Summary SwissPAR for Colibiogen Oral, the Patient information was not yet

available. As soon as the medicine becomes available in Switzerland, the Patient information will be made available on the following website: www.swissmedicin.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 Public Summary SwissPAR.

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.