swissmedic

Summary report on authorisation dated 1 June 2026

BCG-medac® (active substance: live, attenuated Bacillus Calmette-Guérin (BCG) (RIVM))

Authorisation in Switzerland: 5 March 2026

Powder and solvent for suspension for the treatment of non-invasive urothelial bladder carcinoma

About the medicinal product

BCG-medac contains weakened (attenuated) Mycobacterium bovis bacteria for direct instillation in the bladder.

BCG-medac is used to treat various types of bladder cancer. It is effective in cases where the cancer only affects the cells that line the inside of the bladder (urothelium) and has not penetrated the deeper tissues of the bladder.

If the bladder cancer occurs in the form of flat lesions (carcinoma *in situ*), BCG-medac is used to treat disease that is restricted to the mucous membranes of the bladder. There are various grades for categorising cancer growth that affects the mucous membranes of the bladder and the layer of cells beneath them (lamina propria).

BCG-medac is also used to prevent a recurrence of the cancer (preventive treatment).

BCG-medac was authorised under Article 14 paragraph 1 letter a^{bis} of the Therapeutic Products Act (TPA). The Therapeutic Products Act makes provision for the authorisation of certain categories of medicines under 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 BCG-medac is based on the medicinal product of the same name (BCG-medac), which contains the same active substance and has been authorised in Germany in a comparable indication and dosage for more than 10 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 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 BCG-medac, the Information for healthcare professionals and Patient information were not yet available. As soon as the medicinal product becomes available in Switzerland, the medicinal product information 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.