swissmedic

Public Summary SwissPAR dated 18 November 2022

BCG Apogepha® (active substance: live, attenuated Bacillus Calmette-Guérin (Moreau))

First authorisation in Switzerland: 28 July 2022

Medicinal product (powder and solvent for suspension) for the treatment of urothelial carcinoma of the urinary bladder.

Information on authorisation

The medicinal product BCG Apogepha contains the active substance live, attenuated Bacillus Calmette-Guérin (Moreau). It comprises a powder and solvent for a suspension for intravesical use[1]. BCG Apogepha is used to treat superficial, epithelial, non-muscle invasive urothelial cancer[2] of the urinary bladder (Ta, Tis, T1 urothelial carcinoma). BCG Apogepha should not be used in invasive urinary bladder cancer as the chances of complete recovery are negligible.

BCG Apogepha 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 BCG Apogepha is based on the medicinal product Onko BCG, which contains the same active substance and has been authorised for a comparable indication, dosage and use in Poland 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 SwissPAR (Swiss Public Assessment Report) and the resulting Public Summary SwissPAR have therefore not been met. Swissmedic refers to the authorisation of the foreign comparator medicinal product:

https://www.ema.europa.eu

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).

[1] Intravesical use: In intravesical use, the medicinal product is administered directly into the urinary bladder.

[2] Urothelial cancer: Urothelial cancer refers to bladder cancer and cancers of the urinary tract (renal pelvis, ureter or urethra).

Further information on the medicinal product

At the time of publication of the Public Summary SwissPAR for BCG Apogepha, the Information for healthcare professionals was not yet available. As soon as the medicine 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 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.