

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for BCG-medac (Bacillus Calmette-Guérin, BCG)

This is a summary of the risk management plan (RMP) for BCG-medac. The RMP details important risks of BCG-medac, how these risks can be minimised, and how more information will be obtained about BCG-medac's risks and uncertainties (missing information).

BCG-medac's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how BCG-medac should be used.

Important new concerns or changes to the current ones will be included in updates of BCG-medac's RMP.

I. The medicine and what it is used for

BCG-medac is authorised for the treatment of non-invasive urothelial bladder carcinoma (see SmPC for the full indication). It contains Bacillus Calmette-Guérin (BCG) as the active substance and it is administered by intravesical instillation.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of BCG-medac, together with measures to minimise such risks and the proposed studies for learning more about BCG-medac's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size – the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status – the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In the case of BCG-medac, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

In addition to these measures, information about adverse events is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

II.A List of important risks and missing information

Important risks of BCG-medac are risks that need special risk management activities to further investigate or minimise these risks, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of an association to the treatment with BCG-medac. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	— Severe systemic BCG infections incl. · BCG sepsis · Abscesses · Vascular infections · Infections of implants and surrounding tissue — Missing or delayed diagnosis of severe systemic BCG infections
Important potential risks	— None
Missing information	— None

II.B Summary of important risks

Severe systemic BCG infections incl.	
• BCG sepsis • Abscesses • Vascular infections • Infections of implants and surrounding tissue	
Evidence for linking the risk to the medicine	Literature, medac's pharmacovigilance database
Risk factors and risk groups	Traumatic catheterisation or instillations given too early after transurethral resection of bladder cancer. Other potential risk factors are underlying immunosuppression or advanced age.
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2, 4.4, 4.8 and 5.3 SmPC section 4.2 recommends the use of sufficient quantity of lubricant to reduce the risk of traumatising the urinary mucosa and consecutive severe complications. SmPC section 4.4 primarily recommends consulting an infectious disease specialist in case of a suspected BCG infection or flare-up of latent BCG infection and withholding treatment in case of an infection. SmPC section 4.8 gives treatment recommendations for severe systemic infections/reactions. PL sections 2 and 4 Prescription only medicine Additional risk minimisation measures: None

Missing or delayed diagnosis of severe systemic BCG infections	
Evidence for linking the risk to the medicine	Literature, medac's pharmacovigilance database
Risk factors and risk groups	Risk factors are a long latency period between BCG exposure and systemic BCG infection and non-specific symptoms of the disease. In elderly or debilitated patients, a correct and early diagnosis is particularly important to avoid fatal consequences.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 and 4.8 SmPC sections 4.4 and 4.8 recommend educating the patient regarding the possibility of late flare-up of latent BCG infections and actions if symptoms of tuberculosis occur. PL section 2 Prescription only medicine

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Missing or delayed diagnosis of severe systemic BCG infections	
	Additional risk minimisation measures: Patient alert card, announced via Direct Healthcare Professional Communication (DHPC)

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1.8.2 Risk Management Plan

Page: 32/47

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of BCG-medac.

II.C.2 Other studies in the post-authorisation development plan

There are no studies required for BCG-medac.