

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

Attachment
August 24, 2026

【Therapeutic category】 639 Other biological preparations
【Non-proprietary name】 Freeze-dried Bacillus Calmette-Guérin (BCG) for intravesical use (Japanese strain)
【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated in the following patients.) Patients receiving anticancer therapy (such as cytotoxic chemotherapy or radiotherapy)	2. CONTRAINDICATIONS (This drug is contraindicated in the following patients.) Patients receiving anticancer therapy (such as cytotoxic chemotherapy or radiotherapy; <u>however, excluding durvalumab (genetical recombination))</u>)
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION (N/A)	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION <u>For the dosage and administration when used in combination with durvalumab (genetical recombination), refer to the electronic package insert for durvalumab (genetical recombination). This product should be administered only when the benefits are considered to outweigh the risks after patients have been sufficiently informed of the risk of disseminated BCG infection.</u>

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

10. INTERACTIONS			10. INTERACTIONS		
10.1 Contraindications for Co-administration (Do not co-administer with the following.)			10.1 Contraindications for Co-administration (Do not co-administer with the following.)		
Drugs	Signs, symptoms, and treatment	Mechanism/risk factors	Drugs	Signs, symptoms, and treatment	Mechanism/risk factors
Immunosuppressants Ciclosporin Tacrolimus Azathioprine, etc. Corticosteroids at immunosuppressive doses Anticancer therapy (such as cytotoxic chemotherapy or radiotherapy)	Disseminated Bacillus Calmette-Guerin infection may occur. The effect of this drug may be reduced.	Immunosuppressive therapy not only decreases patients' immune response to this product but may also increase the risk of disseminated BCG infection.	Immunosuppressants Ciclosporin Tacrolimus Azathioprine, etc. Corticosteroids at immunosuppressive doses Anticancer therapy (such as cytotoxic chemotherapy or radiotherapy; <u>however, excluding durvalumab (genetical recombination)</u>)	Disseminated Bacillus Calmette-Guerin infection may occur. The effect of this drug may be reduced.	Immunosuppressive therapy not only decreases patients' immune response to this product but may also increase the risk of disseminated BCG infection.

N/A: Not Applicable. No corresponding description is included in the current PRECAUTIONS.

Note: The wavy-underlined text indicates revisions made through consultations concerning drug regulatory procedures in accordance with the Notification entitled "Handling of Approval Applications, etc. for Drugs, Medical Devices, and Regenerative Medical Products Used in Combination with Other Drugs" (PSB/PED Notification No. 0531-1, PSB/MDED Notification No. 0531-3, and PSB/PSD Notification No. 0531-1 dated May 31, 2024).

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