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Translated by
Pharmaceuticals and Medical Devices Agency



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.

Revision of Precautions

Freeze-dried BCG vaccine

(for percutaneous use)

August 22, 2019

Therapeutic category

Vaccines

Non-proprietary name

Freeze-dried BCG vaccine

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p><u>Systemically disseminated</u> BCG infection:</p> <p>When individuals with immunodeficiency syndrome are vaccinated, BCG may be disseminated in the bloodstream to the whole body and produce a miliary tuberculosis-like lesion.</p> <p><u>(When systemically disseminated BCG infection is suspected, appropriate measures should be taken immediately, such as administration of anti-tuberculous drugs.)</u></p> <p><u>Osteitis, osteomyelitis, periostitis:</u></p> <p>Osteitis, osteomyelitis, and periostitis may occur.</p> <p><u>(When osteitis, osteomyelitis, or periostitis is suspected, appropriate measures should be taken, such as administration of anti-tuberculous drugs.)</u></p>	<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>BCG infection:</p> <p><u>Meningitis, osteitis, osteomyelitis, or periostitis</u> may occur. When individuals with immunodeficiency syndrome are vaccinated, BCG may be disseminated in the bloodstream to the whole body and produce miliary tuberculosis-like lesions, <u>resulting in systemically disseminated BCG infection.</u> When BCG infection is suspected, appropriate measures should be taken immediately, such as administration of anti-tuberculous drugs.</p>

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