

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.

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 Smallpox Vaccine Prepared in Cell Culture

July 4, 2024

Therapeutic category

Vaccines

Non-proprietary name

Freeze-dried smallpox vaccine prepared in cell culture

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
(N/A)	<p><u>5. PRECAUTIONS CONCERNING INDICATIONS</u></p> <p><u>Prior to vaccination to patients with human immunodeficiency virus infection, it should be confirmed that CD4-positive cell count is 200 cells/μL or more. There is no experience of administering this vaccine to patients with human immunodeficiency virus infection whose CD4-positive cell count is less than 200 cells/μL.</u></p>
<p>14. PRECAUTIONS CONCERNING USE</p> <p>(N/A)</p>	<p>14. PRECAUTIONS CONCERNING USE</p> <p><u>Storage of Vaccine before Reconstitution</u></p> <p><u>Refrigerated Storage</u></p> <p><u>(1) This vaccine can be stored at 2 to 8°C for 2 years.</u></p> <p><u>(2) Once the vaccine is moved to refrigerated storage, it should be used without being returned to frozen storage within the expiration period and within 2 years after being moved to refrigerated storage.</u></p> <p><u>Storage at Room Temperature</u></p> <p><u>(1) This vaccine can be stored for 4 weeks at room temperature (37°C or below).</u></p> <p><u>(2) Once this vaccine is moved to room temperature storage, it should be used without being returned to frozen or refrigerated storage within the expiration period and within 4 weeks after</u></p>

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	<p><u>being moved to room temperature storage.</u></p> <p><u>Storage of Vaccine after Reconstitution</u></p> <p><u>After reconstitution with the provided diluent, the vaccine should be used within 24 hours when it is stored at room temperature (37°C or below). When the vaccine is stored refrigerated (2 to 6°C), it should be used within one month.</u></p> <p><u>This vaccine does not contain preservatives. Therefore, caution should be exercised to prevent bacterial contamination properly when it is reconstituted and stored in polypropylene cryotubes, etc. after being dispensed. The vaccine solution in a vial whose stopper has been removed in a non-sterile environment should be used immediately. The solution remaining in the vial must always be disposed of without being stored again and used for the next vaccination.</u></p>
<p>Precautions Concerning Administration of the Vaccine</p> <p>Administration of Vaccine</p> <p><u>This vaccine should be reconstituted immediately before administration. The vaccine should be used immediately once it has been reconstituted.</u></p> <p>Before reconstituting the vaccine, the container stopper and its</p>	<p>Precautions Concerning Administration of the Vaccine</p> <p>Administration of Vaccine</p> <p>(deleted)</p> <p>Before reconstituting the vaccine, the container stopper and its</p>

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surroundings should be disinfected using alcohol. After that, the vaccine should be homogeneously reconstituted with 0.5 ml of provided diluent. After reconstitution, the rubber stopper should be removed by cutting the metal cap. The tip of the bifurcated needle should be soaked in the solution, and vaccine solution appropriate for one recipient should be sucked out. Doses for more than 50 recipients can be collected from the reconstituted vaccine solution using the dedicated bifurcated needle.

This vaccine does not contain preservatives as additives.
Therefore, once the stopper has been removed from the vial, the solution remaining in the vial must always be disposed of without being stored again and used for the next vaccination.

(N/A)

surroundings should be disinfected using alcohol. After that, the vaccine should be homogeneously reconstituted with 0.5 ml of provided diluent. After reconstitution, the rubber stopper should be removed by cutting the metal cap. The tip of the bifurcated needle should be soaked in the solution, and vaccine solution appropriate for one recipient should be sucked out.

(deleted)

In cases such as mass vaccination where a large number of persons need to be inoculated consecutively, approximately more than 250 recipients can be vaccinated if the 0.5 mL of vaccine solution is prepared by reconstituting this vaccine with 0.5 mL of provided diluent and bifurcated needles for smallpox vaccination with a single collection volume of $1 \pm 0.5 \mu\text{L}$ (specified value) are used.

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

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