

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

Tarlatamab (genetical recombination)

September 17, 2025

Therapeutic category

Other antitumor agents

Non-proprietary name

Tarlatamab (genetical recombination)

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

Current	Revision
<p>1. WARNINGS</p> <p>Severe cytokine release syndrome and neurologic events (including immune effector cell-associated neurotoxicity syndrome) may occur. This drug should be administered under appropriately arranged conditions, such as inpatient management, particularly during the initial phase of treatments.</p> <p>Severe cytokine release syndrome may occur. In addition to taking preventive measures such as administration of premedication against cytokine release syndrome, patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken in accordance with instructions, such as the guidance for management of cytokine release syndrome, provided by the marketing authorization holder.</p> <p>Severe neurologic events (including immune effector cell-associated neurotoxicity syndrome) may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures should be taken in accordance with instructions, such as the guidance for management of immune effector cell-associated neurotoxicity syndrome, provided by the marketing authorization holder.</p>	<p>1. WARNINGS</p> <p>Severe cytokine release syndrome and neurologic events (including immune effector cell-associated neurotoxicity syndrome) may occur. <u>Since cases involving cytokine release syndrome that resulted in death have also been reported, caution should be exercised for the following:</u></p> <p><u>1</u> This drug should be administered under appropriately arranged conditions, such as inpatient management, particularly during the initial phase of treatments.</p> <p><u>2</u> Severe cytokine release syndrome may occur. In addition to taking preventive measures such as administration of premedication against cytokine release syndrome, patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken in accordance with instructions, such as the guidance for management of cytokine release syndrome, provided by the marketing authorization holder.</p> <p><u>3</u> Severe neurologic events (including immune effector cell-associated neurotoxicity syndrome) may occur. Patients should be carefully monitored, and if any abnormalities are observed, appropriate measures should be taken in accordance with instructions, such as the guidance for management of immune effector cell-associated neurotoxicity syndrome, provided by the marketing authorization holder.</p>