

Published by  
Ministry of Health, Labour and Welfare



Translated by  
Pharmaceuticals and Medical Devices Agency



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*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

## Teicoplanin

May 13, 2022

### **Therapeutic category**

Antibiotic preparations acting mainly on gram-positive bacteria

### **Non-proprietary name**

Teicoplanin

### **Safety measure**

Precautions should be revised in the package insert.

**Pharmaceuticals and Medical Devices Agency**

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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>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythroderma (exfoliative dermatitis):</p> <p>Toxic epidermal necrolysis, oculomucocutaneous syndrome, or erythroderma (exfoliative dermatitis) may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.</p>	<p>Adverse Reactions</p> <p>Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), <u>acute generalised exanthematous pustulosis</u>, erythroderma (exfoliative dermatitis):</p> <p>Toxic epidermal necrolysis, oculomucocutaneous syndrome, <u>acute generalised exanthematous pustulosis</u>, or erythroderma (exfoliative dermatitis) may occur. Patients should be carefully monitored, and if any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.</p>

Note: Designated as a drug requiring preparation of a Drug Guide for Patients

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythroderma (exfoliative dermatitis)</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), <u>acute generalised exanthematous pustulosis</u>, erythroderma (exfoliative dermatitis)</p>

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