

*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

## Preparations containing sulfamethoxazole sodium (OTC antibacterial ophthalmic solution) Preparations containing sulfamethoxazole (OTC antibacterial ophthalmic solution)

August 27, 2024

### **Therapeutic category**

Antibacterial ophthalmic solution

### **Non-proprietary name**

Preparations containing sulfamethoxazole sodium (OTC antibacterial ophthalmic solution)

Preparations containing sulfamethoxazole (OTC antibacterial ophthalmic solution)

### **Safety measure**

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision				
<p>When not to use the product (If the patient does not follow the instructions, the current symptoms may be aggravated, or adverse reactions may occur.) (N/A)</p> <p>Consultation If the following symptoms are observed after using this drug, these may be adverse reactions. In such cases, the use of this drug should be immediately discontinued, and a physician, pharmacist or registered salesclerk should be consulted presenting them with this document. (N/A)</p>	<p>When not to use the product (If the patient does not follow the instructions, the current symptoms may be aggravated, or adverse reactions may occur.) <u>This drug product should not be used in the following persons:</u> <u>Persons who have had an allergic symptom to this product or ingredients of this product</u></p> <p>Consultation If the following symptoms are observed after using this drug, these may be adverse reactions. In such cases, the use of this drug should be immediately discontinued, and a physician, pharmacist or registered salesclerk should be consulted presenting them with this document. <u>The following serious symptoms may occur rarely. In such a case, medical attention should be sought immediately.</u></p> <table border="1" data-bbox="1133 927 1962 1267"> <thead> <tr> <th data-bbox="1133 927 1469 975"><u>Name of symptoms</u></th> <th data-bbox="1473 927 1962 975">Symptoms</th> </tr> </thead> <tbody> <tr> <td data-bbox="1133 978 1469 1267"><u>Shock (anaphylaxis)</u></td> <td data-bbox="1473 978 1962 1267"><u>Symptoms such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after use.</u></td> </tr> </tbody> </table>	<u>Name of symptoms</u>	Symptoms	<u>Shock (anaphylaxis)</u>	<u>Symptoms such as itching of skin, urticaria, hoarseness, sneezing, itchy throat, breathing difficulties, palpitations, and clouding of consciousness may occur immediately after use.</u>
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N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.