

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

## Chloramphenicol (preparations for otic use)

## Fosfomicin sodium (preparations for otic use)

## Gentamicin sulfate (injections)

September 8, 2020

### **Therapeutic category**

Agents for otic and nasal use, antibiotic preparations acting mainly on gram-positive and gram-negative bacteria

### **Non-proprietary name**

Chloramphenicol, fosfomicin sodium, gentamicin sulfate

### **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
(N/A)	<u>Precautions concerning Indications</u> <u>For the treatment of otitis media, the Guidance for Appropriate Use of Antimicrobials should be consulted to decide whether administration of antimicrobials is necessary, and then this drug should be administered in cases where treatment with this drug is determined to be appropriate.</u>

N/A: Not Applicable, because the section is not included in the current package insert.

<Reference> Guidance for Appropriate Use of Antimicrobials compiled by the Tuberculosis and Infectious Diseases Control Division, of the Health Bureau, at the Ministry of Health, Labour and Welfare

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