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Translated by
Pharmaceuticals and Medical Devices Agency



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

Azithromycin hydrate (oral dosage form for pediatric use), erythromycin, clarithromycin, spiramycin acetate, roxithromycin, tosufloxacin tosilate hydrate (oral dosage form without dosage and administration for pediatric use), norfloxacin (oral dosage form with indications for otitis media)

September 8, 2020

Therapeutic category

Antibiotics preparations acting mainly on gram-positive bacteria and mycoplasma, synthetic antibacterials

Non-proprietary name

Azithromycin hydrate, erythromycin, clarithromycin, spiramycin acetate, roxithromycin, tosufloxacin tosilate hydrate, norfloxacin

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
<p>Precautions concerning Indications</p> <p>For the treatment of pharyngitis/laryngitis, tonsillitis, acute bronchitis, infectious enteritis, or sinusitis, 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.</p> <p>*Highlighted indications should be listed only when applicable.</p>	<p>Precautions concerning Indications</p> <p>For the treatment of pharyngitis/laryngitis, tonsillitis, acute bronchitis, infectious enteritis, <u>otitis media,</u> or sinusitis, 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.</p> <p>*Highlighted indications should be listed only when applicable.</p>

<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

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>5. PRECAUSIONS CONCERNING INDICATIONS</p> <p><Pharyngitis/laryngitis, tonsillitis, acute bronchitis, infectious enteritis, or sinusitis></p> <p>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</p>	<p>5. PRECAUSIONS CONCERNING INDICATIONS</p> <p><Pharyngitis/laryngitis, tonsillitis, acute bronchitis, infectious enteritis, <u>otitis media,</u> or sinusitis></p> <p>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</p>

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