



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

Cefmenoxime hydrochloride (preparations for otic and nasal use), chloramphenicol (solution for topical use, oral dosage form), tetracycline hydrochloride (powders, capsules), polymixin B sulfate (powders), clindamycin hydrochloride, clindamycin phosphate (injections), benzylpenicillin potassium, benzylpenicillin benzathine hydrate, lincomycin hydrochloride hydrate, aztreonam, amoxicillin hydrate, ampicillin hydrate, ampicillin sodium, potassium clavulanate/amoxicillin hydrate, dibekacin sulfate (injections), sultamicillin tosilate hydrate, cefaclor, cefazolin sodium, cefazolin sodium hydrate, cephalexin (oral dosage form with indications for otitis media), cefalotin sodium, cefixime hydrate, cefepime dihydrochloride hydrate, ceftazidime hydrochloride, cefotiam hydrochloride (intravenous injections), cefcapene pivoxil hydrochloride hydrate, cefditoren pivoxil, cefdinir, ceftazidime hydrate, cefteteram pivoxil, ceftriaxone sodium hydrate, cefpodoxime proxetil, cefroxadine hydrate, cefuroxime axetil, tebipenem pivoxil, doripenem hydrate, bacampicillin hydrochloride, panipenem/betamipron, faropenem sodium hydrate, flomoxef sodium, fosfomycin calcium hydrate, meropenem hydrate, chloramphenicol sodium succinate, demethylchlortetracycline hydrochloride, doxycycline hydrochloride hydrate, minocycline hydrochloride (oral dosage form), kanamycin sulfate

September 8, 2020

Therapeutic category

Agents for otic and nasal use, dermatics for purulence, antibiotic preparations acting mainly on gram-positive bacteria, antibiotic preparations acting mainly on gram-negative bacteria, antibiotic preparations acting mainly on gram-positive and gram-negative bacteria, antibiotic preparations acting mainly on gram-positive and gram-negative bacteria, rickettsia and chlamydia, antibiotic preparations acting mainly on acid-fast bacteria

Non-proprietary name

Cefmenoxime hydrochloride, chloramphenicol, tetracycline hydrochloride, polymixin B sulfate, clindamycin hydrochloride, clindamycin phosphate, benzylpenicillin potassium, benzylpenicillin benzathine hydrate, lincomycin hydrochloride hydrate, aztreonam, amoxicillin hydrate, ampicillin hydrate, ampicillin sodium, potassium clavulanate/amoxicillin hydrate, dibekacin sulfate, sultamicillin tosilate hydrate, cefaclor, cefazolin sodium, cefazolin sodium hydrate, cephalexin, cefalotin sodium, cefixime hydrate, cefepime dihydrochloride hydrate, ceftazidime hydrochloride, cefotiam hydrochloride, cefcapene pivoxil hydrochloride hydrate, cefditoren pivoxil, cefdinir, ceftazidime hydrate, cefteteram pivoxil, ceftriaxone sodium hydrate, cefpodoxime proxetil, cefroxadine hydrate, cefuroxime axetil, tebipenem pivoxil, doripenem hydrate, bacampicillin hydrochloride, panipenem/betamipron, faropenem sodium hydrate, flomoxef sodium, fosfomicin calcium hydrate, meropenem hydrate, chloramphenicol sodium succinate, demethylchlortetracycline hydrochloride, doxycycline hydrochloride hydrate, minocycline hydrochloride, kanamycin 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
<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

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