



Summary of investigation results

Azithromycin hydrate

September 15, 2015

Non-proprietary name

Azithromycin hydrate

Brand name (Marketing authorization holder)

Zithromac Tablets 250 mg, Zithromac Capsules for pediatric use 100 mg, Zithromac Fine Granules for pediatric use 10%, Zithromac SR Dry Syrup 2 g, Zithromac Tablets 600 mg, Zithromac Intravenous Infusions 500 mg and the others (Pfizer Japan Inc. and others)

Indications

Refer to the attachment below.

Summary of revision

“Drug-induced hypersensitivity syndrome” should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of drug-induced hypersensitivity syndrome or drug rash with eosinophilia and systemic syndrome have been reported in patients treated with azithromycin hydrate both in Japan and overseas. In addition, the company core datasheet (CCDS)* has been updated. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.



This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A case associated with drug-induced hypersensitivity syndrome has been reported (a causal relationship to the product could not be established for this patient). No fatality has been reported.

NOTE:

*CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.



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Attachment

Brand name	Indication
Zithromac Tablets 250 mg	Applicable microorganisms: Azithromycin-susceptible strains of genus <i>Staphylococcus</i> , genus <i>Streptococcus</i> , genus <i>Pneumococcus</i> , <i>Neisseria gonorrhoeae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Haemophilus influenzae</i> , <i>Legionella pneumophila</i> , genus <i>Peptostreptococcus</i> , genus <i>Prevotella</i> , genus <i>Chlamydia</i> , genus <i>Mycoplasma</i> Applicable conditions: Deep skin infections, lymphangiitis/lymphadenitis, pharyngitis/laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, lung abscess, secondary infection of chronic respiratory lesions, urethritis, cervicitis, pelvic inflammatory disease, sinusitis, periodontal inflammation, pericoronitis, jaw inflammation
Zithromac Capsules for pediatric use 100 mg, Zithromac Fine Granules for pediatric use 10%	Applicable microorganisms: Azithromycin-susceptible strains of genus <i>Staphylococcus</i> , genus <i>Streptococcus</i> , genus <i>Pneumococcus</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Haemophilus influenzae</i> , <i>Chlamydophila pneumoniae</i> , genus <i>Mycoplasma</i> Applicable conditions: Pharyngitis/laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, lung abscess, otitis media



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Brand name	Indication
Zithromac SR Dry Syrup 2 g	Applicable microorganisms: Azithromycin-susceptible strains of genus <i>Staphylococcus</i> , genus <i>Streptococcus</i> , genus <i>Pneumococcus</i> , <i>Neisseria gonorrhoeae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Haemophilus influenzae</i> , genus <i>Peptostreptococcus</i> , genus <i>Chlamydia</i> , genus <i>Mycoplasma</i> Applicable conditions: Deep skin infection, lymphangiitis/lymphadenitis, pharyngitis/laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, lung abscess, secondary infection of chronic respiratory lesion, urethritis, cervicitis, sinusitis, periodontal inflammation, pericoronitis, jaw inflammation
Zithromac Tablets 600 mg	Applicable microorganisms: <i>Mycobacterium avium</i> complex Applicable conditions: Prophylaxis of and treat disseminated <i>Mycobacterium avium</i> complex associated with acquired immunodeficiency syndrome

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Brand name	Indication
Zithromac Intravenous Infusions 500 mg	Applicable microorganisms: Azithromycin-susceptible strains of genus <i>Staphylococcus</i> , genus <i>Streptococcus</i> , genus <i>Pneumococcus</i> , <i>Neisseria gonorrhoeae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Haemophilus influenzae</i> , <i>Legionella pneumophila</i> , genus <i>Peptostreptococcus</i> , genus <i>Prevotella</i> , genus <i>Chlamydia</i> , genus <i>Mycoplasma</i> Applicable conditions: Pneumonia, pelvic inflammatory disease

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