



# Summary of investigation results

## Azithromycin hydrate

August 3, 2017

### Non-proprietary name

Azithromycin hydrate

### Brand name (Marketing authorization holder)

- a. Zithromax Tablets 250 mg (Pfizer Japan Inc.) and the others
- b. Zithromax Tablets 600 mg (Pfizer Japan Inc.)
- c. Zithromax Capsules for Pediatric Use 100 mg and Zithromax Fine Granules for Pediatric Use 10% (Pfizer Japan Inc.) and the others
- d. Zithromax SR Dry Syrup 2g (Pfizer Japan Inc.)
- e. Zithromax Intravenous Use 500 mg (Pfizer Japan Inc.)

### Indications

See Attachment

### Summary of revision

“Acute generalized exanthematous pustulosis” should be added in the Clinically Significant Adverse Reactions section.

### Background of the revision and investigation results

Cases of “Acute generalized exanthematous pustulosis” have been reported in patients treated with azithromycin hydrate both in Japan and overseas. In addition, the company core data sheet (CCDS) has been revised. Following investigation results based on opinions of the expert advisors and the available evidence, the MHLW/PMDA concluded that the revision of the package insert was necessary.

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

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A case of acute generalized exanthematous pustulosis has been reported (a causal relationship to the product could not be ruled out for this patient). No fatality has been reported.



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Product	Launched in Japan	Indications
a.	June 2000	<Applicable microorganisms> Azithromycin hydrate-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> , and genus <i>Mycoplasma</i> <Applicable conditions> Deep-seated skin infections, lymphangitis/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, and jaw inflammation
b.	January 2002	<Applicable microorganisms> <i>Mycobacterium avium</i> complex (MAC) <Applicable conditions> Inhibition and treatment of disseminated <i>Mycobacterium avium</i> complex (MAC) disease associated with acquired immunodeficiency syndrome (AIDS)
c.	June 2000 (capsules) September 2009 (fine granules for pediatric use)	<Applicable microorganisms> Azithromycin hydrate-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>Chlamydia pneumoniae</i> , and genus <i>Mycoplasma</i> <Applicable conditions> Pharyngitis/laryngitis, tonsillitis (including peritonsillitis, peritonsillar abscess), acute bronchitis, pneumonia, lung abscess, and otitis media

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d.	April 2009	<p>&lt;Applicable microorganisms&gt;            Azithromycin hydrate-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>, and genus <i>Mycoplasma</i></p> <p>&lt;Applicable conditions&gt;            Deep-seated skin infections, lymphangitis/lymphadenitis, pharyngitis/laryngitis, tonsillitis (including peritonsillitis and peritonsillar abscess), acute bronchitis, pneumonia, lung abscess, secondary infection of chronic respiratory lesions, urethritis, cervicitis, sinusitis, periodontal inflammation, pericoronitis, and jaw inflammation</p>
e.	December 2011	<p>&lt;Applicable microorganisms&gt;            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>, and genus <i>Mycoplasma</i></p> <p>&lt;Applicable conditions&gt;            Pneumonia and pelvic inflammatory disease</p>