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Summary of Investigation Results

Azelnidipine Olmesartan medoxomil/azelnidipine Clarithromycin Vonoprazan fumarate/amoxicillin hydrate/clarithromycin Rabeprazole sodium/amoxicillin hydrate/clarithromycin

March 17, 2026

Non-proprietary name

- a. Azelnidipine
- b. Olmesartan medoxomil/azelnidipine
- c. Clarithromycin
- d. Vonoprazan fumarate/amoxicillin hydrate/clarithromycin
- e. Rabeprazole sodium/amoxicillin hydrate/clarithromycin

Brand name (marketing authorization holder)

- a. Calblock Tablets 8 mg, 16 mg (Daiichi Sankyo Co., Ltd.), and others
- b. Rezaltas Combination Tablets LD, HD (Daiichi Sankyo Co., Ltd.)
- c. Klaricid Tablets 200 mg, Klaricid Tablets 50 mg for Pediatric Use (Nippon Chemiphar Co., Ltd.), Clarith tablets 200, Clarith tablets 50 for pediatric, Clarith dry syrup 10% for pediatric (Taisho Pharmaceutical Co., Ltd.), and others
- d. Vonosap Pack 400, 800 (Takeda Pharmaceutical Company Limited)
- e. Rabecure Pack 400, 800 (Eisai Co., Ltd.)

Japanese market launch

- a. May 2003

Pharmaceuticals and Medical Devices Agency

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Contact: <https://www.pmda.go.jp/english/contact/0001.html>



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- b. April 2010
- c. June 1991 (Tablets 200 mg), October 1991 (Tablets 50 mg for Pediatric Use)
June 1991 (tablets 200), October 1991 (tablets 50 for pediatric), December 1996 (dry syrup 10% for pediatric)
- d. June 2016
- e. February 2014

Indications

See attachment.

Summary of revisions

a., b.

1. "Clarithromycin" should be added to the 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) section.
2. "Clarithromycin" should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

c., d., e.

1. Azelnidipine and olmesartan medoxomil/azelnidipine should be added to the 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) section.
2. Azelnidipine and olmesartan medoxomil/azelnidipine should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

Investigation results and background of the revision

The pharmacokinetic effects and post-marketing safety information concerning co-administration of azelnidipine with clarithromycin were evaluated. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revising PRECAUTIONS to list the co-administration of these drugs in the Contraindications for Co-administration section was necessary for the following reason:

- Based on the analysis of physiological pharmacokinetic models, when azelnidipine is co-administered with clarithromycin 400 mg or 800 mg, it is expected that the AUC of azelnidipine increases approximately 3.4-fold or 5.4-fold, raising concerns about the occurrence of adverse reactions.



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Of note, opinions from relevant academic societies were solicited regarding the influence on clinical settings of contraindicating co-administration of clarithromycin and preparations containing azelnidipine, which revealed no specific concerns.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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Attachment

Number	Non-proprietary name	Indications
a.	Azelnidipine	Hypertension
b.	Olmesartan medoxomil/azelnidipine	Hypertension
c.	Clarithromycin	<Klaricid Tablets 200 mg, Clarith tablets 200> ○ Common infection <Applicable microorganisms> Clarithromycin-susceptible strains of genus <i>Staphylococcus</i> , genus <i>Streptococcus</i> , <i>Streptococcus pneumoniae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Haemophilus influenzae</i> , genus <i>Legionella</i> , genus <i>Campylobacter</i> , genus <i>Peptostreptococcus</i> , genus <i>Chlamydia</i> , genus <i>Mycoplasma</i> <Applicable conditions> Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, secondary infections following trauma, thermal burn, and surgical wound, perianal abscess, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, lung abscess, secondary infection of chronic respiratory lesions, urethritis, cervicitis, infectious enteritis, otitis media, sinusitis, periodontal inflammation, pericoronitis, jaw inflammation ○ Nontuberculous mycobacteriosis <Applicable microorganisms>

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	<p>Clarithromycin-susceptible strains of genus <i>Mycobacterium</i> <Applicable conditions> Nontuberculous mycobacteriosis including <i>Mycobacterium avium</i> complex (MAC) ○ <i>Helicobacter pylori</i> infection <Applicable microorganisms> Clarithromycin-susceptible strains of <i>Helicobacter pylori</i> <Applicable conditions> <i>Helicobacter pylori</i> infection of the stomach after endoscopic treatment for gastric/duodenal ulcer, MALT lymphoma of the stomach, immune thrombocytopenia, and early stage of gastric cancer, and <i>Helicobacter pylori</i> gastritis</p> <p><Klaricid Tablets 50 mg for Pediatric Use, Clarith tablets 50 for pediatric, Clarith dry syrup 10% for pediatric> ○ Common infection <Applicable microorganisms> Clarithromycin-susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Streptococcus pneumoniae</i>, <i>Moraxella (Branhamella) catarrhalis</i>, <i>Haemophilus influenzae</i>, genus <i>Legionella</i>, <i>Bordetella pertussis</i>, genus <i>Campylobacter</i>, genus <i>Chlamydia</i>, genus <i>Mycoplasma</i> <Applicable conditions></p>
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		<p>Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, secondary infections following trauma, thermal burn, and surgical wound, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, lung abscess, secondary infection of chronic respiratory lesions, infectious enteritis, otitis media, sinusitis, scarlet fever, pertussis</p> <p>○ Disseminated mycobacterium avium complex (MAC) associated with acquired immunodeficiency syndrome (AIDS)</p> <p><Applicable microorganisms></p> <p>Clarithromycin-susceptible <i>Mycobacterium avium</i> complex (MAC)</p> <p><Applicable conditions></p> <p>Disseminated mycobacterium avium complex (MAC) associated with acquired immunodeficiency syndrome (AIDS)</p>
d.	Vonoprazan fumarate/amoxicillin hydrate/clarithromycin	<p><Applicable microorganisms></p> <p>Amoxicillin/clarithromycin-susceptible strains of <i>Helicobacter pylori</i></p> <p><Applicable conditions></p> <p><i>Helicobacter pylori</i> infection of the stomach after endoscopic treatment for gastric/duodenal ulcer, MALT lymphoma of the stomach, immune thrombocytopenia, and early stage of gastric cancer, and <i>Helicobacter pylori</i> gastritis</p>



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e.	Rabeprazole sodium/amoxicillin hydrate/clarithromycin	<Applicable microorganisms> Amoxicillin/clarithromycin-susceptible strains of <i>Helicobacter pylori</i> <Applicable conditions> <i>Helicobacter pylori</i> infection of the stomach after endoscopic treatment for gastric/duodenal ulcer, MALT lymphoma of the stomach, immune thrombocytopenia, and early stage of gastric cancer, and <i>Helicobacter pylori</i> gastritis
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