



Summary of Investigation Results

Fluoroquinolones (oral and injectable dosage forms)

January 10, 2019

Non-proprietary name

- a. Moxifloxacin hydrochloride
- b. Tosufloxacin tosilate hydrate
- c. Levofloxacin hydrate
- d. Sitafloracin hydrate
- e. Ciprofloxacin hydrochloride hydrate
- f. Ciprofloxacin
- g. Garenoxacin mesilate hydrate
- h. Prulifloxacin
- i. Ofloxacin
- j. Norfloxacin
- k. Lomefloxacin hydrochloride
- l. Pazufloxacin mesilate

Brand name (Marketing authorization holder)

- a. Avelox Tablets 400 mg (Bayer Yakuhi, Ltd.)
- b. Ozex Tab. 75, 150, Ozex fine granules 15% for pediatric, Ozex Tab. 60 mg for pediatric (Fuji Film Toyama Chemical Co., Ltd.), Tosuxacin Tablets 75 mg, 150 mg (Mylan EPD G.K), and the others
- c. Cravit Tablets 250 mg, 500 mg, Cravit Fine Granules 10%, Cravit Intravenous Drip Infusion Bag 500 mg/100 mL, Cravit Intravenous Drip Infusion 500 mg/20 mL (Daiichi Sankyo Co., Ltd.), and the others
- d. Gracevit Tablets 50 mg, Gracevit Fine Granules 10% (Daiichi Sankyo Co., Ltd.), and

the others

- e. Ciproxan Tablets 100, 200 (Bayer Yakuhin, Ltd.), and the others
- f. Ciproxan-I.V. 200, 400 (Bayer Yakuhin, Ltd.), and the others
- g. Geninax Tablets 200 mg (Fuji Film Toyama Chemical Co., Ltd.)
- h. Sword Tablets 100 (Meiji Seika Pharma Co., Ltd.)
- i. Tarivid Tablets 100 mg (Daiichi Sankyo Co., Ltd.), and the others
- j. Baccidal Tablets 100 mg, 200 mg, Baccidal Tablets for Children 50 mg (Kyorin Pharmaceutical Co., Ltd.), and the others
- k. Bareon Capsule 100 mg, Bareon Tablets 200 mg (Mylan EPD G.K.)
- l. Pasil Intravenous Drip Infusion 300 mg, 500 mg, 1000 mg (Fuji Film Toyama Chemical Co., Ltd.), Pazucross Injection 300 mg, 500 mg, 1000 mg (Mitsubishi Tanabe Pharma Corporation)

Indications

See Attachment

Summary of revisions

- a., b. (oral preparations for pediatric use), c., f., g., i., k., l.
 1. “Patients complicated with aortic aneurysm or aortic dissection, or patients who have a previous history, a family history or risk factors (Marfan's syndrome, etc.) of aortic aneurysm or aortic dissection“ should be added to the Careful Administration section.
 2. A statement should be added to the Important Precautions section that patients should be carefully monitored and instructed to seek medical attention immediately if they experience symptoms such as pain in the abdomen, chest, or back, and Imaging assessment should be considered if necessary for the type of patients defined in 1 above as the specific patient population to be addressed by the package insert.
 3. “Aortic aneurysm, aortic dissection” should be added to the Clinically Significant Adverse Reactions section.

- b. (oral dosage forms except for oral preparations for pediatric use), d., e., h., j.
 1. “Patients complicated with aortic aneurysm or aortic dissection, or patients who have a previous history, a family history or risk factors (Marfan's syndrome, etc.) of aortic aneurysm or aortic dissection“ should be added to the Careful Administration section.
 2. An Important Adverse Reactions section should be newly added and a statement

should be included that patients should be carefully monitored and instructed to seek medical attention immediately if they experience symptoms such as pain in the abdomen, chest, or back, and imaging assessment should be considered if necessary for the type of patients defined in 1 above as the specific patient population to be addressed by the package insert.

3. “Aortic aneurysm, aortic dissection” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Results of several epidemiological studies (Lee CC et al. JAMA Intern Med. 2015, Daneman N et al. BMJ Open 2015, Pasternak B et al. BMJ 2018, Lee CC et al. J Am Coll Cardiol. 2018) and a non-clinical study (LeMaire SA et al. JAMA Surg. 2018) have suggested an association between fluoroquinolone use and development of aortic aneurysm or aortic dissection, and the necessity of revision of relevant package inserts was accordingly considered. In the Expert Discussion, while revision of the package inserts for drug products of this class based on the findings reported in these studies was generally supported by the expert advisors, in consideration of the current lack of relevant Japanese data, one advisor suggested further accumulation of data in Japan before discussing the necessity of revision. MHLW/PMDA focused on the consistency of findings identified among the aforementioned multiple epidemiological studies and concluded that revision of the package insert was necessary at this time based on the opinions of the expert advisors and their deliberations at the Expert Discussion.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

a. to I.

No cases involving aortic aneurysm or aortic dissection have been reported to date



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Attachment

Branded name (MAH)	Indications
a. Avelox Tablets 400 mg (Bayer Yakuhin, Ltd.)	<Applicable microorganisms> Moxifloxacin-susceptible strains of genus <i>Staphylococcus</i> , genus <i>Streptococcus</i> , genus <i>Pneumococcus</i> , <i>Moraxella</i> (<i>Branhamella</i>) <i>catarrhalis</i> , <i>Escherichia coli</i> , genus <i>Klebsiella</i> , genus <i>Enterobacter</i> , genus <i>Proteus</i> , <i>Haemophilus influenzae</i> , <i>Legionella pneumophila</i> , <i>Propionibacterium acnes</i> , <i>Chlamydia</i> <i>pneumonia</i> , <i>Mycoplasma pneumonia</i> <Applicable conditions> Superficial skin infections, deep-seated skin infections, secondary infections following trauma, thermal burn, and surgical wound; pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions, sinusitis
b. Ozex Tab. 75, 150 (Fuji Film Toyama Chemical Co., Ltd.), Tosuxacin Tablets 75mg, 150mg (Mylan EPD G.K)	<Applicable microorganisms> Tosufloxacin-susceptible strains of genus <i>Staphylococcus</i> , genus <i>Streptococcus</i> , <i>Pneumococcus</i> (including penicillin- resistant <i>Pneumococcus</i>), genus <i>Enterococcus</i> , <i>Neisseria</i> <i>gonorrhoeae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Bacillus</i> <i>anthrax</i> , <i>Escherichia coli</i> , <i>Shigella</i> , genus <i>Salmonella</i> , <i>Salmonella typhi</i> , <i>Salmonella enterica serovar Paratyphi A</i> , genus <i>Citrobacter</i> , genus <i>Klebsiella</i> , genus <i>Enterobacter</i> , genus <i>Serratia</i> , genus <i>Proteus</i> , <i>Morganella morganii</i> , genus <i>Providencia</i> , <i>Vibrio cholerae</i> , <i>Haemophilus influenzae</i> , <i>Pseudomonas aeruginosa</i> , <i>Burkholderia cepacia</i> , <i>Stenotrophomonas (Xanthomonas) maltophilia</i> , genus <i>Acinetobacter</i> , genus <i>Peptostreptococcus</i> , genus <i>Bacteroides</i> , genus <i>Prevotella</i> , <i>Propionibacterium acnes</i> , <i>Chlamydia trachomatis</i>

	<p><Applicable conditions></p> <ul style="list-style-type: none"> · Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, acne (with suppurative inflammation) · Secondary infections following trauma, thermal burn, and surgical wound; mastitis, perianal abscess · Osteomyelitis, arthritis · Pharyngitis/laryngitis, tonsillitis (including peritonsillar abscess), acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions · Cystitis, pyelonephritis, prostatitis (acute/chronic), epididymitis, urethritis · Cholecystitis, cholangitis · Infectious enteritis, typhoid, paratyphoid, cholera · Bartholinitis, intrauterine infection, uterine adnexitis · Dacryocystitis, hordeolum, meibomianitis · Otitis externa, otitis media, sinusitis, purulent sialoadenitis · Periodontal inflammation, pericoronitis, jaw inflammation · Anthrax
<p>b. Ozex fine granules 15% for pediatric, Ozex Tab. 60 mg for pediatric (Fuji Film Toyama Chemical Co., Ltd.)</p>	<p><Applicable microorganisms></p> <p>Tosufloxacin-susceptible strains of <i>Pneumococcus</i> (including penicillin-resistant <i>Pneumococcus</i>), <i>Moraxella (Branhamella) catarrhalis</i>, <i>Bacillus anthrax</i>, <i>Vibrio cholerae</i>, <i>Haemophilus influenzae</i>, <i>Mycoplasma pneumonia</i></p> <p><Applicable conditions></p> <p>Pneumonia, cholera, otitis media, anthrax</p>
<p>c. Cravit Tablets 250 mg, 500 mg, Cravit Fine Granules 10% (Daiichi Sankyo Co., Ltd.)</p>	<p><Applicable microorganisms></p> <p>Susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Neisseria gonorrhoeae</i>, <i>Moraxella (Branhamella) catarrhalis</i>, <i>Bacillus anthrax</i>, <i>Mycobacterium tuberculosis</i>, <i>Escherichia coli</i>, <i>Shigella</i>, genus <i>Salmonella</i>, <i>Salmonella typhi</i>, <i>Salmonella enterica</i></p>

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	<p><i>serovar Paratyphi A</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>Morganella morgani</i>, genus <i>Providencia</i>, <i>Yersinia pestis</i>, <i>Vibrio cholerae</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Acinetobacter</i>, genus <i>Legionella</i>, genus <i>Brucella</i>, <i>Francisella tularensis</i>, genus <i>Campylobacter</i>, genus <i>Peptostreptococcus</i>, <i>Propionibacterium acnes</i>, Q fever rickettsia (<i>Coxiella burnetii</i>), <i>Chlamydia trachomatis</i>, <i>Chlamydia pneumonia</i>, <i>Mycoplasma pneumonia</i></p> <p><Applicable conditions></p> <p>Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, acne (with suppurative inflammation), secondary infections following trauma, thermal burn, and surgical wound; mastitis, perianal abscess, pharyngitis/laryngitis, tonsillitis (including peritonsillitis, peritonsillar abscess), acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute/chronic), epididymitis, urethritis, cervicitis, cholecystitis, cholangitis, infectious enteritis, typhoid, paratyphoid, cholera, bartholinitis, intrauterine infection, uterine adnexitis, dacryocystitis, hordeolum, meibomianitis, otitis externa, otitis media, sinusitis, purulent sialoadenitis, periodontal inflammation, pericoronitis, jaw inflammation, anthrax, brucellosis, plague, tularaemia, pulmonary tuberculosis and other tuberculosis, Q fever</p>
<p>c. Cravit Intravenous Drip Infusion Bag 500 mg/100 mL, Cravit Intravenous Drip Infusion 500 mg/20 mL (Daiichi Sankyo Co., Ltd.)</p>	<p><Applicable microorganisms></p> <p>Levofloxacin-susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Moraxella (Branhamella) catarrhalis</i>, <i>Bacillus anthrax</i>, <i>Escherichia coli</i>, <i>Salmonella typhi</i>, <i>Salmonella enterica serovar Paratyphi A</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>Morganella</i></p>

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	<p><i>morganii</i>, genus <i>Providencia</i>, <i>Yersinia pestis</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Acinetobacter</i>, genus <i>Legionella</i>, genus <i>Brucella</i>, <i>Francisella tularensis</i>, genus <i>Peptostreptococcus</i>, genus <i>Prevotella</i>, Q fever rickettsia (<i>Coxiella burnetii</i>), <i>Chlamydia trachomatis</i>, <i>Chlamydia pneumonia</i>, <i>Mycoplasma pneumonia</i></p> <p><Applicable conditions></p> <p>Secondary infections following trauma, thermal burn, and surgical wound; pneumonia, secondary infections of chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute/chronic), epididymitis, peritonitis, cholecystitis, cholangitis, typhoid, paratyphoid, intrauterine infection, uterine adnexitis, anthrax, brucellosis, plague, tularaemia, Q fever</p>
<p>d. Gracevit Tablets 50 mg, Gracevit Fine Granules 10% (Daiichi Sankyo Co., Ltd.)</p>	<p><Applicable microorganisms></p> <p>Susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Moraxella (Branhamella) catarrhalis</i>, <i>Escherichia coli</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>Morganella morganii</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, <i>Legionella pneumophila</i>, genus <i>Peptostreptococcus</i>, genus <i>Prevotella</i>, genus <i>Porphyromonas</i>, genus <i>Fusobacterium</i>, <i>Chlamydia trachomatis</i>, <i>Chlamydia pneumonia</i>, <i>Mycoplasma pneumoniae</i></p> <p><Applicable conditions></p> <ul style="list-style-type: none"> · Pharyngitis/laryngitis, tonsillitis (including peritonsillitis, peritonsillar abscess), acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions · Cystitis, pyelonephritis, urethritis · Cervicitis · Otitis media, sinusitis · Periodontal inflammation, pericoronitis, jaw inflammation

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<p>e. Ciproxan Tablets 100, 200 (Bayer Yakuhin, Ltd.)</p>	<p><Applicable microorganisms> Ciprofloxacin-susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Neisseria gonorrhoeae</i>, <i>Bacillus anthrax</i>, <i>Escherichia coli</i>, <i>Shigella</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>Morganella morganii</i>, genus <i>Providencia</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Acinetobacter</i>, genus <i>Legionella</i>, genus <i>Peptostreptococcus</i></p> <p><Applicable conditions> Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, secondary infections following trauma, thermal burn, and surgical wound; mastitis, perianal abscess, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute/chronic), epididymitis, urethritis cholecystitis, cholangitis, infectious enteritis, bartholinitis, intrauterine infection, uterine adnexitis, dacryocystitis, hordeolum, meibomianitis, otitis media, sinusitis, anthrax</p>
<p>f. Ciproxan-I.V. 200, 400 (Bayer Yakuhin, Ltd.)</p>	<p>Adults</p> <p><Applicable microorganisms> Susceptible strains of genus <i>Staphylococcus</i>, genus <i>Enterococcus</i>, <i>Bacillus anthrax</i>, <i>Escherichia coli</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Legionella</i></p> <p><Applicable conditions> Sepsis, secondary infections following trauma, thermal burn, and surgical wound; pneumonia, peritonitis, cholecystitis, cholangitis, anthrax</p> <p>Pediatric use (1) General infectious diseases</p>

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	<p><Applicable microorganisms> Susceptible strains of <i>Bacillus anthrax</i>, <i>Escherichia coli</i>, <i>Pseudomonas aeruginosa</i></p> <p><Applicable conditions> Complicated cystitis, pyelonephritis, anthrax</p> <p>(2) Improvement of symptoms associated with respiratory infection caused by <i>Pseudomonas aeruginosa</i> in patients with cystic fibrosi</p>
g. Geninax Tablets 200 mg (Fuji Film Toyama Chemical Co., Ltd.)	<p><Applicable microorganisms></p> <p>Garenoxacin-susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i> (including penicillin-resistant <i>Pneumococcus</i>), <i>Moraxella (Branhamella) catarrhalis</i>, <i>Escherichia coli</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, <i>Haemophilus influenzae</i>, <i>Legionella pneumophila</i>, <i>Chlamydia pneumonia</i>, <i>Mycoplasma pneumonia</i></p> <p><Applicable conditions></p> <p>Pharyngitis/laryngitis, tonsillitis (including peritonsillitis, peritonsillar abscess), acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions, otitis media, sinusitis</p>
h. Sword Tablets 100 (Meiji Seika Pharma Co., Ltd.)	<p><Applicable microorganisms></p> <p>Ulifloxacin (the active substance of the drug)-susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Moraxella (Branhamella) catarrhalis</i>, <i>Escherichia coli</i>, <i>Shigella</i>, genus <i>Salmonella</i>(excluding <i>Salmonella typhi</i>, <i>Salmonella enterica</i> serovar <i>Paratyphi A</i>), genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>vibrio cholera</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Peptostreptococcus</i></p> <p><Applicable conditions></p> <p>Superficial skin infections, deep-seated skin infections, chronic pyoderma, secondary infections following trauma, thermal burn,</p>

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	and surgical wound; perianal abscess, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute/chronic), cholecystitis, cholangitis, infectious enteritis, cholera, intrauterine infection, uterine adnexitis, hordeolum, otitis media, sinusitis
i. Tarivid Tablets 100 mg (Daiichi Sankyo Co., Ltd.)	<p><Applicable microorganisms></p> <p>Susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Neisseria gonorrhoeae</i>, <i>Mycobacterium leprae</i>, <i>Escherichia coli</i>, <i>Shigella</i>, <i>Salmonella typhi</i>, <i>Salmonella enterica serovar Paratyphi A</i>, genus <i>Citrobacter</i>, <i>Klebsiella pneumonia</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>Morganella morganii</i>, genus <i>Providencia</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Acinetobacter</i>, genus <i>Campylobacter</i>, genus <i>Peptostreptococcus</i>, <i>Chlamydia trachomatis</i></p> <p><Applicable conditions></p> <p>Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, secondary infections following trauma, thermal burn, and surgical wound; mastitis, perianal abscess, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, secondary infections of chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute/chronic), epididymitis, urethritis, cervicitis, cholecystitis, cholangitis, infectious enteritis, typhoid, paratyphoid, Bartholin's glanditis, intrauterine infection, uterine adnexitis, dacryocystitis, hordeolum, meibomianitis, keratitis (including corneal ulcer), otitis media, sinusitis, periodontal inflammation, pericoronitis, jaw inflammation, leprosy</p>
j. Baccidal Tablets 100 mg, 200 mg (Kyorin Pharmaceutical Co.,	<p><Applicable microorganisms></p> <p>Susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Neisseria</i></p>



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Ltd.)	<p><i>gonorrhoeae, Bacillus anthrax, Escherichia coli, Shigella</i>, genus <i>Salmonella, Salmonella typhi, Salmonella enterica serovar Paratyphi A</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus, Morganella morgani, Providencia rettgeri, vibrio cholera, Vibrio parahaemolyticus, Haemophilus influenzae, Pseudomonas aeruginosa, Francisella tularensis</i>, genus <i>Campylobacter</i></p> <p><Applicable conditions></p> <p>Superficial skin infections, deep-seated skin infections, chronic pyoderma, pharyngitis/laryngitis, tonsillitis, acute bronchitis, cystitis, pyelonephritis, prostatitis (acute/chronic), urethritis, cholecystitis, cholangitis, infectious enteritis, typhoid, paratyphoid, cholera, otitis media, sinusitis, anthrax, tularaemia</p>
j. Baccidal Tablets for Children 50 mg (Kyorin Pharmaceutical Co., Ltd.)	<p><Applicable microorganisms></p> <p>Susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus, Pneumococcus</i>, genus <i>Enterococcus, Bacillus anthrax, Escherichia coli, Shigella</i>, genus <i>Salmonella, Salmonella typhi, Salmonella enterica serovar Paratyphi A</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Proteus, Morganella morgani, Haemophilus influenzae, Pseudomonas aeruginosa, Francisella tularensis</i>, genus <i>Campylobacter</i></p> <p><Applicable conditions></p> <p>Superficial skin infections, chronic pyoderma, pharyngitis/laryngitis, tonsillitis, acute bronchitis, cystitis, pyelonephritis, infectious enteritis, typhoid, paratyphoid, anthrax, tularaemia</p>
k. Bareon Capsule 100 mg, Bareon Tablets 200 mg (Mylan EPD G.K.)	<p><Applicable microorganisms></p> <p>Lomefloxacin-susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus, Pneumococcus</i>, genus <i>Enterococcus, Neisseria gonorrhoeae, Moraxella (Branhamella) catarrhalis, Escherichia coli, Shigella</i>, genus <i>Salmonella</i>, genus <i>Citrobacter</i>,</p>

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	<p>genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>Morganella morganii</i>, genus <i>Providencia</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Acinetobacter</i>, genus <i>Campylobacter</i>, genus <i>Peptostreptococcus</i></p> <p><Applicable conditions></p> <ul style="list-style-type: none"> • Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma • Secondary infections following trauma, thermal burn, and surgical wound; mastitis, perianal abscess • Osteomyelitis, arthritis • Acute bronchitis, pneumonia, lung abscess, secondary infections of chronic respiratory lesions • Cystitis, pyelonephritis, prostatitis (acute/chronic), urethritis • Infectious enteritis • Bartholinitis, intrauterine infection, uterine adnexitis • Abscess of eyelid, dacryocystitis, hordeolum, meibomianitis, keratitis (including corneal ulcer) • Otitis media, sinusitis • Periodontal inflammation, pericoronitis, jaw inflammation
<p>I. Pasil Intravenous Drip Infusion 300 mg, 500 mg, 1000 mg (Fuji Film Toyama Chemical Co., Ltd.), Pazucross Injection 300 mg, 500 mg, 1000 mg (Mitsubishi Tanabe Pharma Corporation)</p>	<p><Applicable microorganisms></p> <p>Pazufloxacin-susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus</i>, <i>Pneumococcus</i>, genus <i>Enterococcus</i>, <i>Moraxella (Branhamella) catarrhalis</i>, <i>Escherichia coli</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Serratia</i>, genus <i>Proteus</i>, <i>Morganella morganii</i>, genus <i>Providencia</i>, <i>Haemophilus influenzae</i>, <i>Pseudomonas aeruginosa</i>, genus <i>Acinetobacter</i>, genus <i>Legionella</i>, genus <i>Bacteroides</i>, genus <i>Prevotella</i></p> <p><Applicable conditions></p> <ul style="list-style-type: none"> • Sepsis • Secondary infections following trauma, thermal burn and surgical wound



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	<ul style="list-style-type: none">• Pneumonia, lung abscess, secondary infections of chronic respiratory lesions• Complicated cystitis, pyelonephritis, prostatitis (acute/chronic)• Peritonitis, intra-abdominal abscess• Cholecystitis, cholangitis, liver abscess• Uterine adnexitis, parametritis
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