



Summary of Investigation Results

Fluoroquinolones and quinolones (oral and injectable dosage forms)

September 24, 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
- m. Pipemidic acid hydrate

Branded name (Marketing authorization holder)

- a. Avelox Tablets 400 mg (Bayer Yakuhin, 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

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- 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 mg, 200 mg (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 (Alfresa Pharma Corporation), 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)
 - m. Dolcol Tablets 250 mg (Nichi-Iko Pharmaceutical Co., Ltd.), and the others

Indications

See Attachment

Summary of revisions

a.

The language concerning “tendon disorders such as tendinitis and tendon rupture” in the Clinically Significant Adverse Reactions section should be revised to “tendon disorders such as Achilles tendinitis and tendon rupture” and the descriptions of initial symptoms, etc. should be updated.

b.

1. “Peripheral neuropathy” should be added to the Clinically Significant Adverse Reactions section.
2. “Tendon disorders such as Achilles tendinitis and tendon rupture” should be added to the Clinically Significant Adverse Reactions section.
3. “Psychiatric symptoms” should be added to the Clinically Significant Adverse

Reactions section.

c., i.

1. "Peripheral neuropathy" should be added to the Clinically Significant Adverse Reactions section.
2. The descriptions of initial symptoms, etc. in the language concerning "tendon disorders such as Achilles tendinitis and tendon rupture" in the Clinically Significant Adverse Reactions section should be updated.

d.

1. "Tendon disorders such as Achilles tendinitis and tendon rupture" should be added to the Clinically Significant Adverse Reactions section.

e., f.

The descriptions of initial symptoms in the language concerning "tendon disorders such as Achilles tendinitis and tendon rupture" in the Clinically Significant Adverse Reactions section should be updated.

g.

1. "Peripheral neuropathy" should be added to the Clinically Significant Adverse Reactions section.
2. "Tendon disorders such as Achilles tendinitis and tendon rupture" should be added to the Clinically Significant Adverse Reactions section.

h., m.

1. "Tendon disorders such as Achilles tendinitis and tendon rupture" should be added to the Clinically Significant Adverse Reactions section.
2. "Psychiatric symptoms" should be added to the Clinically Significant Adverse Reactions section.

j.

1. Initial symptoms, etc. should be added to the language concerning "tendon disorders such as Achilles tendinitis and tendon rupture" in the Clinically Significant Adverse Reactions section.

k.

1. "Psychiatric symptoms" should be added to the Clinically Significant Adverse

Reactions section.

2. The descriptions of initial symptoms, etc. in the language concerning “tendon disorders such as Achilles tendinitis and tendon rupture” in the Clinically Significant Adverse Reactions section should be updated.

I.

Initial symptoms should be added to the language concerning “tendon disorders such as Achilles tendinitis and tendon rupture” in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

According to a foreign measure report regarding the disabling and potentially permanent adverse reactions (tendon-, psychiatric-, or neurological-related adverse reactions) associated with fluoroquinolone and quinolone antibacterials, the European package inserts have been revised following the US revision. In response to the report, the necessity of revision of relevant package inserts in Japan was discussed based on information from cases of the adverse reactions reported in Japan, published papers, etc.

While a certain level of precaution for tendon disorders and psychiatric symptoms is included in the current package insert of a number of fluoroquinolone and quinolone antibacterials in Japan, in the discussion, collagen tissue disorders and suppression of GABA nerves, etc. were suggested as the mechanisms of onset of tendon disorders and psychiatric symptoms, respectively. It was also suggested that these mechanisms are risks common to all the antibacterials of these classes. MHLW/PMDA concluded that revision of the package insert was necessary to include a precaution in all fluoroquinolone and quinolone antibacterials based on the results of their investigation of the currently available evidence and in consultation with expert advisors. As for peripheral neuropathy, there is not enough information on the mechanisms of onset or epidemiological findings to indicate that this event is a risk common to all fluoroquinolones and quinolones, and it was not considered necessary to revise relevant package inserts in a uniform manner at this time. Nevertheless, cases have been reported in Japan in patients treated with tosufloxacin tosilate hydrate, levofloxacin hydrate, and garenoxacin mesilate hydrate, and although cases have not been reported in patients treated with ofloxacin in Japan, ofloxacin is the racemic body of levofloxacin. Consequently, MHLW/PMDA also concluded that revision of the package insert was



necessary with respect to peripheral neuropathy based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

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

Cases involving peripheral neuropathy

b.

No cases have been reported to date.

c.

A total of 6 cases have been reported to date (including 2 cases for which a causal relationship between the drug and event could not be ruled out).

One instance of patient mortality has been reported to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

g., i.

No cases have been reported to date.

Cases involving tendon disorders

a., b.

No cases have been reported to date.

c.

A total of 36 cases* have been reported to date.

No patient mortality has been reported to date.

d. to m.

No cases have been reported to date.

Cases involving psychiatric symptoms

b., h., k., m.

No cases have been reported to date.

*A causal relationship between the drug and event was not evaluated.



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 (Branhamella) 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 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 75 mg, 150 mg (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 gonorrhoeae</i> , <i>Moraxella (Branhamella) catarrhalis</i> , <i>Bacillus 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> <Applicable conditions> |

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| | <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> 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> 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> 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 serovar</i></p> |

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| | <p><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>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> <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, Bartholin's glanditis, 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 <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> <Applicable conditions>Sepsis, secondary infections following trauma, thermal burn, and surgical wound; pneumonia, peritonitis, cholecystitis, cholangitis, anthrax 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 fibrosis</p> |
| <p>g. Geninax Tablets 200 mg (Fuji Film Toyama Chemical Co., Ltd.)</p> | <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> |
| <p>h. Sword Tablets 100 (Meiji Seika Pharma Co., Ltd.)</p> | <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 (Alfresa Pharma Corporation) | <Applicable microorganisms> 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</i> serovar <i>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> <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, cervicitis, cholecystitis, cholangitis, infectious enteritis, typhoid, paratyphoid, bartholinitis, intrauterine infection, uterine adnexitis, dacryocystitis, hordeolum, meibomianitis, keratitis (including corneal ulcer), otitis media, sinusitis, periodontal inflammation, pericoronitis, jaw inflammation, leprosy |
| j. Baccidal Tablets 100 mg, 200 mg | <Applicable microorganisms> Susceptible strains of genus <i>Staphylococcus</i> , genus |

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| <p>(Kyorin Pharmaceutical Co., Ltd.)</p> | <p><i>Streptococcus, Pneumococcus, genus Enterococcus, Neisseria gonorrhoeae, Bacillus anthrax, Escherichia coli, Shigella, genus Salmonella, Salmonella typhi, Salmonella enterica serovar Paratyphi A, genus Citrobacter, genus Klebsiella, genus Enterobacter, genus Serratia, genus Proteus, Morganella morganii, Providencia rettgeri, vibrio cholera, Vibrio parahaemolyticus, Haemophilus influenzae, Pseudomonas aeruginosa, Francisella tularensis, genus 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> |
| <p>j. Baccidal Tablets for Children 50 mg (Kyorin Pharmaceutical Co., Ltd.)</p> | <p><Applicable microorganisms></p> <p>Susceptible strains of genus <i>Staphylococcus</i>, genus <i>Streptococcus, Pneumococcus, genus Enterococcus, Bacillus anthrax, Escherichia coli, Shigella, genus Salmonella, Salmonella typhi, Salmonella enterica serovar Paratyphi A, genus Citrobacter, genus Klebsiella, genus Enterobacter, genus Proteus, Morganella morganii, Haemophilus influenzae, Pseudomonas aeruginosa, Francisella tularensis, genus 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> |
| <p>k. Bareon Capsules 100 mg, Bareon Tablets 200 mg (Mylan EPD G.K.)</p> | <p><Applicable microorganisms></p> <p>Lomefloxacin-susceptible strains of genus <i>Staphylococcus, genus Streptococcus, Pneumococcus, genus Enterococcus, Neisseria gonorrhoeae, Moraxella (Branhamella) catarrhalis, Escherichia</i></p> |

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| | <p><i>coli, Shigella, genus Salmonella, genus Citrobacter, genus Klebsiella, genus Enterobacter, genus Serratia, genus Proteus, Morganella morganii, genus Providencia, Haemophilus influenzae, Pseudomonas aeruginosa, genus Acinetobacter, genus Campylobacter, genus 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 |



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| | <p>surgical wound</p> <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 |
| <p>m. Dolcol Tablets 250 mg (Nichi-Iko Pharmaceutical Co., Ltd.)</p> | <p><Applicable microorganisms> Pipemidic acid-susceptible strains of <i>Escherichia coli</i>, <i>Shigella</i>, genus <i>Citrobacter</i>, genus <i>Klebsiella</i>, genus <i>Enterobacter</i>, genus <i>Proteus</i>, <i>Vibrio parahaemolyticus</i>, <i>Pseudomonas aeruginosa</i> <Applicable conditions> Cystitis, pyelonephritis, prostatitis (acute/chronic), infectious enteritis, otitis media, sinusitis</p> |