



Summary of Investigation Results

Tosufloxacin tosilate hydrate (for oral use)

April 19, 2018

Non-proprietary name

Tosufloxacin tosilate hydrate (for oral use)

Brand name (Marketing authorization holder)

Ozex Tab. 75, 150, Ozex fine granules 15% for pediatric (Toyama Chemical Co., Ltd.) and the others

Tosuxacin Tablets 75 mg, 150 mg (Mylan EPD G.K) and the others

Indications

See Attachment

Summary of revision

“Nephrogenic diabetes insipidus” should be added to the language concerning acute kidney injury and interstitial nephritis in the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of nephrogenic diabetes insipidus have been reported in patients treated with tosufloxacin tosilate hydrate (for oral use) in Japan. Based on the results of their investigation of the evidence currently available and in consultation with expert advisors, 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.

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

A total of 2 cases associated with nephrogenic diabetes insipidus have been reported to date (a causal relationship with the product could not be ruled out for these cases).

No patient mortalities have been reported to date.



Attachment

Product	Indications
<p>Ozex Tab. 75, 150 Tosuxacin Tablets 75mg, 150mg and the others</p>	<p><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</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>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> 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</p>



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	Anthrax
Ozex fine granules 15% for pediatric and the others	<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> <Applicable conditions> Pneumonia, cholera, otitis media, anthrax