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Summary of Investigation Results

Tosufloxacin tosilate hydrate (oral dosage form)

November 26, 2025

Non-proprietary name

Tosufloxacin tosilate hydrate (oral dosage form)

Brand name (marketing authorization holder)

Ozex Tab. 75, Ozex Tab. 150, Ozex fine granules 15% for pediatric, Ozex Tab. 60 mg for pediatric (Fuji Film Toyama Chemical Co., Ltd.), Tosuxacin Tablets 75 mg, Tosuxacin Tablets 150 mg (Viartis Pharmaceuticals Japan G.K.), and the others

Japanese market launch

Tablets 150 mg: April 1990, Tablets 75 mg: July 1990

Fine granules 15% for pediatric: January 2010

Tablets 60 mg for pediatric: July 2018

Indications

See Attachment

Summary of revisions

"Calculus urinary" should be added to "Acute kidney injury, nephritis interstitial, nephrogenic diabetes insipidus" in the "11.1 Clinically Significant Adverse Reactions" section in the "11. ADVERSE REACTIONS", and precautions concerning acute kidney injury with crystalluria should be added as well.



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Investigation results and background of the revision

Calculus urinary cases and cases of acute kidney injury with crystalluria were evaluated. Cases in which a causal relationship between tosylloxacin tosylate hydrate (oral dosage form) and calculus urinary, the drug and acute kidney injury with crystalluria were reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases and patient mortalities involving calculus urinary and acute kidney injury with crystalluria reported in Japan

Calculus urinary cases *1

A total of 5 cases have been reported to date (including 4 cases in which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported.

Cases of acute kidney injury with crystalluria*1,2

A total of 12 cases have been reported to date (including 7 cases in which a causal relationship between the drug and the event was reasonably possible).

No patient mortalities have been reported.

*1: Cases collected in the PMDA's safety database for drugs

*2: Among cases of adverse reaction (PT) of "crystal nephropathy" or those that fell under MedDRA v28.0 SMQ "acute renal failure" (narrow) and simultaneously reported as adverse reactions (PT) of "medication crystals in urine present", "crystal urine", "crystalluria", or "crystal urine present", those meeting the diagnostic criteria for acute kidney injury in "KDIGO Clinical Practice Guideline for Acute Kidney Injury" were retrieved.

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).

Pharmaceuticals and Medical Devices Agency



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Attachment

Brand name	Indications
Ozex Tab. 75, Ozex Tab. 150 Tosuxacin Tablets 75 mg, Tosuxacin Tablets 150 mg	< Applicable microorganisms > Tosufloxacin-susceptible strains of genus Staphylococcus, genus Streptococcus, Pneumococcus (including penicillin-resistant Pneumococcus), genus Enterococcus, Neisseria gonorrhoeae, Moraxella (Branhamella) catarrhalis, 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, genus Providencia, Vibrio cholerae, Haemophilus influenzae, Pseudomonas aeruginosa, Burkholderia cepacia, Stenotrophomonas (Xanthomonas) maltophilia, genus Acinetobacter, genus Peptostreptococcus, genus Bacteroides, genus Prevotella, Propionibacterium acnes, Chlamydia trachomatis < 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

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Brand name	Indications
	infection, uterine adnexitis, dacryocystitis, hordeolum, meibomianitis, otitis externa, otitis media, sinusitis, purulent sialoadenitis, periodontal inflammation, pericoronitis, jaw inflammation, anthrax
Ozex fine granules 15% for pediatric, Ozex Tab. 60 mg for pediatric	< Applicable microorganisms > Tosufloxacin-susceptible strains of Pneumococcus (including penicillin-resistant Pneumococcus), Moraxella (Branhamella) catarrhalis, Bacillus anthrax, Vibrio cholerae, Haemophilus influenzae, Mycoplasma pneumonia < Applicable conditions > Pneumonia, cholera, otitis media, anthrax