



Summary of investigation results

Doxycycline hydrochloride hydrate

Aug 6, 2014

Non-proprietary Name

Doxycycline hydrochloride hydrate

Brand Name (Marketing Authorization Holder)

Vibramycin tablets 50 mg and 100 mg (Pfizer Japan Inc.)

Indications

Applicable microorganisms:

Doxycycline-susceptible strains of genus *Staphylococcus*, genus *Streptococcus*, *Pneumococcus*, *Neisseria gonorrhoeae*, *Bacillus anthracis*, *Escherichia coli*, *Shigella*, *Klebsiella pneumoniae*, *Yersinia pestis*, *Vibrio cholerae*, genus *Brucella*, *Q fever rickettsia (Coxiella burnetii)*, and genus *Chlamydia*

Applicable conditions:

Superficial skin infections, deep-seated skin infections, lymphangitis/lymphadenitis, chronic pyoderma, secondary infections that are suffered from trauma, thermal burn, and surgical wound, mastitis, osteomyelitis, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, secondary infection of chronic respiratory lesions, cystitis, pyelonephritis, prostatitis (acute/chronic), urethritis, gonococcal infection, enteritis infectious, cholera, intrauterine infection, adnexitis, abscess of eyelid, dacryocystitis, hordeolum, keratitis (including corneal ulcer), otitis media, sinusitis, pericoronitis, purulent sialoadenitis, scarlet fever, anthrax, Brucellosis, Plague, Q fever, and psittacosis

Summary of revision

‘Drug-induced hypersensitivity syndrome’ should be added in Clinically significant adverse reactions section.



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Background of the revision and investigation results

Cases of drug-induced hypersensitivity syndrome have been reported in patients treated with doxycycline in Japan and foreign countries and a company core datasheet (CCDS)* has been updated. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reaction and fatal cases in the last 3 fiscal years

A drug-induced hypersensitivity syndrome case has been reported. A causal relationship with doxycycline was not established in the case. No fatalities has been reported.

NOTE

*CCDS is prepared by a marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.