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, adenitis, 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.
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.