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.

Summary of Investigation Results

Ceftriaxone sodium hydrate

August 2, 2018

Non-proprietary name

Ceftriaxone sodium hydrate

Branded name (Marketing authorization holder)

Rocephin Intravenous 0.5 g, 1 g, Rocephin Infusion bag 1 g (TAIYO Pharma Co., Ltd.), and the others

Indications

Applicable microorganisms:

・Ceftriaxone-susceptible strains of genus *Staphylococcus, genus Streptococcus, Pneumococcus, Neisseria gonorrhoeae, Escherichia coli,* genus *Citrobacter,* genus *Klebsiella,* genus *Enterobacter,* genus *Serratia,* genus *Proteus, Morganella morganii,* genus *Providencia, Haemophilus influenzae,* genus *Peptostreptococcus,* genus *Bacteroides*, and genus *Prevotella* species (except *Prevotella bivia*)

Applicable conditions:

・Sepsis, pharyngitis/laryngitis, tonsillitis, acute bronchitis, pneumonia, lung abscess, pyothorax, infections secondary to chronic respiratory lesions, cystitis, pyelonephritis, epididymitis, urethritis, cervicitis, pelvic inflammatory disease, proctitis, peritonitis, intra-abdominal abscess, cholecystitis, cholangitis, bartholinitis, intrauterine infection, uterine adnexitis, parametritis, suppurative meningitis, keratitis (including corneal ulcer), otitis media, sinusitis, cellulitis around jawbone and jaw inflammation

Summary of revisions

A precaution concerning convulsions and involuntary movements that may occur following

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

use of this drug should be added to the current language related to disturbed consciousness. Subsequently, these sentences in their entirety should be listed as information concerning neuropsychiatric symptoms rather than disturbed consciousness.

Investigation results and background of the revision

Cases of neuropsychiatric symptoms have been reported in patients treated with ceftriaxone sodium hydrate in Japan and overseas. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

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

A total of 19 cases involving neuropsychiatric symptoms have been reported to date (including 11 cases for which a causal relationship with the product could not be ruled out*). One instance of patient mortality has been reported to date (a causal relationship with the product could not be established for this case.)

*No other neuropsychiatric symptoms than disturbed consciousness occurred in 4 cases.

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp