Summary of investigation results

Ceftriaxone sodium hydrate

October 20, 2015

Non-proprietary name

Ceftriaxone sodium hydrate

Brand name (Marketing authorization holder)

Rocephin Intravenous Injections 0.5 g and 1 g, Rocephin Intravenous Infusions Bag 1 g (Chugai Pharmaceutical 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* (except *Prevotella bivia*)

Applicable conditions:

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

Summary of revision

“Acute generalised exanthematous pustulosis” should be added to the “toxic epidermal necrolysis and oculomucocutaneous syndrome” subsection in the Clinically significant adverse reaction section.

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Background of the revision and investigation results

Cases of acute generalised exanthematous pustulosis have been reported in patients treated with ceftriaxone sodium hydrate both in Japan and overseas. In addition, the company core datasheet (CCDS)* has been updated. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

A case associated with acute generalised exanthematous pustulosis has been reported (a causal relationship to the product could not be established for this patient). No fatality has been reported.

NOTE:

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

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