# Summary of investigation results

## Cefotaxime sodium

April 23, 2015

### Non-proprietary name

cefotaxime sodium

### Brand name (Marketing authorization holder)

Claforan Injections 0.5 g and 1 g (Sanofi K.K.)

Cefotax Injections 0.5 g and 1 g (Nichi-iko Sanofi K.K.)

### Indications

Applicable microorganisms:

Cefotaxime-sensitive strains of genus *Streptococcus*, *Streptococcus pneumoniae*, *Escherichia coli*, genus *Citrobacter*, genus *Klebsiella*, genus *Enterobacter*, genus *Serratia*, genus *Proteus*, *Morganella morganii*, genus *Providencia*, *Haemophilus influenzae*, genus *Peptostreptococcus*, and genus *Bacteroides*

Applicable conditions:

Sepsis, infective endocarditis, secondary infections that are suffered from trauma, thermal burn, and surgical wound, acute bronchitis, pneumonia, lung abscess, pyothorax, secondary infection of chronic respiratory lesions, cystitis, pyelonephritis, peritonitis, cholecystitis, cholangitis, bartholinitis, intrauterine infection, adnexitis, parametritis, pyogenic meningitis

### Summary of revision

‘By other cephem antibiotics’ should be deleted and ‘acute generalised exanthematous pustulosis’ should be added in the toxic epidermal necrolysis and oculomucocutaneous syndrome subsection in the Clinically significant adverse reactions section.

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*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.*

## Background of the revision and investigation results

Cases of toxic epidermal necrolysis and oculomucocutaneous syndrome have been reported in patients treated with cefotaxime sodium both in Japan and overseas. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that 'by other cephem antibiotics' should be deleted in the Clinically significant adverse reactions section.

Cases of acute generalised exanthematous pustulosis have been reported in patients treated with cefotaxime sodium in overseas, and 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

No toxic epidermal necrolysis case has been reported.

No oculomucocutaneous syndrome case has been reported.

No acute generalised exanthematous pustulosis-associated case has been reported.

NOTE

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

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