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
Levetiracetam

May 31, 2016

Non-proprietary name

Levetiracetam

Brand name (Marketing authorization holder)

a. E Keppra Tablets 250 mg, 500 mg, E Keppra Dry Syrup 50 % (UCB Japan Co., Ltd.)

b. E Keppra for I.V. Infusion 500 mg (UCB Japan Co., Ltd.)

Indications

a. Partial onset seizures in epilepsy patients (including secondary generalized seizures)
Concomitant therapy with other antiepileptic drugs for tonic-clonic seizures in epilepsy patients who fail to show a satisfactory response to other antiepileptic drugs

b. As an alternative to levetiracetam oral tablets for the following treatments in patients who are not able to use the oral treatment temporarily:
Partial onset seizures in epilepsy patients (including secondary generalized seizures)
Concomitant therapy with other antiepileptic drugs for tonic-clonic seizures in epilepsy patients who fail to show a satisfactory response to other antiepileptic drugs

Summary of revision

“Acute renal failure” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of acute renal failure have been reported in patients treated with levetiracetam 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.

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

A total of 7 cases associated with acute renal failure [1] have been reported (including 2 cases for which a causal relationship to the product could not be ruled out[2]). Of the 7 cases, 2 fatal cases have been reported (the causal relationship between the product and the fatal outcome could not be established for these cases).

NOTE:

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

[1]Cases in which creatinine or BUN levels are defined as Grade 3 based on the criteria established in the Pharmaceuticals and Chemicals Safety Division, MHLW Notification No. 80, “Classification criteria for severity of adverse drug reactions”, dated June 29, 1992.

[2]Includes 1 case in which rhabdomyolysis occurred and caused acute renal failure.

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