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

October 17, 2017

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 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 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

“Neuroleptic malignant syndrome” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of neuroleptic malignant syndrome have been reported in patients treated with levetiracetam in Japan. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

Pharmaceuticals and Medical Devices Agency
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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan (in and after 2014)

A total of 3 cases associated with neuroleptic malignant syndrome have been reported (including 2 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.

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