



Summary of investigation results

Levetiracetam

January 9, 2015

Non-proprietary Name

levetiracetam

Brand Name (Marketing Authorization Holder)

- a. E Keppra Tablets 250 mg and 500 mg, and E Keppra Dry Syrup 50% (UCB Japan Co. Ltd)
- b. E Keppra Intravenous Infusions 500 mg (UCB Japan Co. Ltd) (This product has not been launched in Japan yet.)

Indications

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

Summary of revision

'Rhabdomyolysis' should be added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of rhabdomyolysis have been reported in patients treated with levetiracetam in Japan. Following an investigation based on the opinions of expert advisors and 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 total of 13 cases of adverse events suggestive of rhabdomyolysis have been reported (including 7 cases in which causality could not be ruled out). No fatalities have been reported.