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

Gabapentin, Gabapentinenacarbil

April 21, 2016

Non-proprietary name

a. Gabapentin

b. Gabapentinenacarbil

Brand name (Marketing authorization holder)

a. Gabapen Tablets 200 mg, 300 mg, 400 mg, Gabapen Syrup 5% (Pfizer Japan Inc.)

b. Regnite Tablets 300 mg (Astellas Pharma Inc.)

Indications

a. Treatment with concomitant antiepileptic drugs for partial seizures (including secondary generalized seizure) in patients with epilepsy for whom other antiepileptic drugs are not sufficiently effective

b. Moderate to severe restless legs syndrome

Summary of revision

a. “Anaphylaxis” should be newly added in the Clinically significant adverse reaction section.

b. “Anaphylaxis” should be newly added in the Clinically significant adverse reaction (similar drug) section.

Background of the revision and investigation results

Cases of anaphylaxis have been reported in patients treated with gabapentin 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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Although case of anaphylaxis has not been reported in patients treated with Gabapentinenacarbil in Japan and overseas, as a pro-drug of gabapentin, 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. No case associated with anaphylaxis has been reported.

b. No case associated with anaphylaxis 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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