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

Lamotrigine

March 21, 2017

Non-proprietary name

Lamotrigine

Brand name (Marketing authorization holder)

a. Lamictal Tablets 25 mg and 100 mg (GlaxoSmithKline K.K.)
b. Lamictal Tablets for pediatrics 2 mg and 5 mg (GlaxoSmithKline K.K.)

Indications

a.

- Monotherapy for the following types of seizures in epileptic patients
  Partial seizures (including secondary generalized seizures)
  Tonic-clonic seizures
  Typical absence seizures
- Concomitant therapy with antiepileptics for the following types of seizures in epileptic patients who have not sufficiently responded to other antiepileptics.
  Partial seizures (including secondary generalized seizures)
  Tonic-clonic seizures
  Generalized seizures of Lennox-Gastaut syndrome
- Suppression of recurrent/relapsed mood episodes in patients with bipolar disorder

b.

- Monotherapy for the following types of seizures in epileptic patients
  Typical absence seizures
- Concomitant therapy with antiepileptics for the following types of seizures in epileptic patients who have not sufficiently responded to other antiepileptics.
  Partial seizures (including secondary generalized seizures)
  Tonic-clonic seizures
  Generalized seizures of Lennox-Gastaut syndrome

Summary of revision

Perampanel and lacosamide should be newly added as drugs that do not affect glucuronidation of lamotrigine in the Precautions of Dosage and Administration section.

Background of the revision and investigation results

Perampanel and lacosamide, both antiepileptics, have been approved in Japan. In the overseas clinical trial data for perampanel and lacosamide, it had been reported that these drugs had no effect on the pharmacokinetics of lamotrigine. 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

N/A

Pharmaceuticals and Medical Devices Agency
Office of Safety I
3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp