



Summary of investigation results

Stribild Combination Tablets

November 24, 2015

Non-proprietary name

Elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate

Brand name (Marketing authorization holder)

Stribild Combination Tablets (Japan Tobacco Inc.)

Indications

HIV-1 infection

Summary of revision

1. “Carbamazepine, phenobarbital, phenytoin, fosphenytoin” should be added in the Contraindications section regarding “Patients being administered the following drugs”.
2. “Carbamazepine, phenobarbital, phenytoin” should be deleted from Precautions for concomitant use subsection, and “Carbamazepine, phenobarbital, phenytoin, fosphenytoin” should be added to the “Contraindications for concomitant use” subsection in the Interactions section.

Background of the revision and investigation results

In the results from the clinical drug interaction study, blood concentration of elvitegravir and cobicistat decreased significantly which may result in loss of therapeutic effect that compared with no concomitant use of carbamazepine, when elvitegravir and cobicistat were administered in combination with carbamazepine. Phenobarbital and phenytoin are also the potent inducers of CYP3A comparable to carbamazepine. According to the study results, the US labels of elvitegravir and cobicistat containing products have been changed to include carbamazepine, phenobarbital, and phenytoin in the Contraindications section. In addition, fosphenytoin is a prodrug of phenytoin.



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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