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

Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir

November 26, 2015

Non-proprietary name

Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir

Brand name (Marketing authorization holder)

Viekirax Combination Tablets (AbbVie G.K.)

Indications

Improvement of viremia in patients with serogroup 1 (genotype 1) chronic hepatitis C or compensated cirrhosis type C

Summary of revision

1. "Patients with hepatic dysfunction (Child–Pugh Class B)" should be added in the Contraindications section.
2. An alert on hepatic failure should be added to the subsection relevant to the assessment of hepatic function in the Important precautions section.
3. "Hepatic failure" should be added to the subsection of hepatic function disorder in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of hepatic failure have been reported overseas in patients treated with ombitasvir hydrate, paritaprevir hydrate, and ritonavir, and the United States package insert was revised after the approval of the application in Japan. 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

No case associated with hepatic failure has been reported.

Pharmaceuticals and Medical Devices Agency
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(National Health Insurance Drug List, as of 26th November 2015)

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