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

Non-proprietary name

Ombitasvir hydrate/Paritaprevir hydrate/Ritonavir

Brand name (Marketing authorization holder)

Viekirax Combination Tablets (AbbVie GK)

Indications

Improvement of viremia in Serological Group 1 (Genotype 1) chronic hepatitis C or compensated cirrhosis C

Summary of revision

1. Conduct of renal function tests before and after the start of administration of this drug and an alert for patients with decreased renal function and patients concomitantly administered calcium channel blockers should be added to the Important Precautions section.
2. “Acute renal failure” should be newly added to the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of acute renal failure have been reported in patients treated with the combination product of ombitasvir hydrate/paritaprevir hydrate/ritonavir in Japan. In addition, there were cases in which renal function suddenly deteriorate among patients with decreased renal function and/or patients concomitantly administered calcium channel blockers. 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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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 14 cases associated with acute renal failure have been reported (including 9 cases for which a causal relationship to the product could not be ruled out). Of the 14 cases, 1 fatal case has been reported (a causal relationship between the product and the fatal outcome could not be ruled out for this patient).

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