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

Asunaprevir, Daclatasvir hydrochloride

July 7, 2015

Non-proprietary name

a. Asunaprevir

b. Daclatasvir hydrochloride

Brand name (Marketing authorization holder)

a. Sunvepra Capsules 100 mg (Bristol-Myers K.K.)

b. Daklinza Tablets 60 mg (Bristol-Myers K.K.)

Indications

a and b

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

Summary of revision

1. An alert on decreased hepatic residual function should be added to the subsection relevant to the assessment of hepatic function in the Important precautions section.
2. '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

Regardless of increased hepatic enzymes, cases associated with decreased hepatic residual function such as decreased albumin level, prolonged prothrombin time, ascites, hepatic encephalopathy, and those resulting in hepatic failure have been reported in patients treated with asunaprevir and daclatasvir hydrochloride 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.

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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 37 cases associated with decreased hepatic residual function have been reported (including 21 cases* for which a causal relationship to the product could not be ruled out). Of the 37 cases, a fatal case has been reported (including a case for which a causal relationship to the product could not be ruled out).

NOTE

*Causal relationship with the combination therapy of asunaprevir and daclatasvir hydrochloride could not be ruled out.

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