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

Daclatasvir hydrochloride, Asunaprevir

April 23, 2015

Non-proprietary name

a. daclatasvir hydrochloride

b. asunaprevir

Brand name (Marketing authorization holder)

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

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

Indications

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

Summary of revision

'Erythema multiforme' should be added to the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of erythema multiforme have been reported in patients treated with daclatasvir hydrochloride and asunaprevir 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

A total of 7 cases associated with erythema multiforme has been reported (including 6 cases* in which causality could not be ruled out). Of the 7 cases, no fatality has been reported.

NOTE:

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

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