



Summary of investigation results

Asunaprevir, Daclatasvir hydrochloride

October 20, 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 1) chronic hepatitis C or compensated cirrhosis type C

Summary of revision

“Interstitial pneumonia” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of interstitial pneumonia 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.



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

A total of 11 cases associated with interstitial pneumonia have been reported (including 4 cases for which a causal relationship to the products could not be ruled out*). No fatality has been reported.

NOTES:

- * A causal relationship with combination therapy of asunaprevir and daclatasvir hydrochloride was evaluated.