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Summary of Investigation Results

Direct-acting antivirals in chronic hepatitis C or hepatic cirrhosis

February 25, 2020

Non-proprietary name

a. Daclatasvir hydrochloride
b. Asunaprevir
c. Sofosbuvir
d. Ledipasvir acetonate/sofosbuvir
e. Elbasvir
f. Grazoprevir hydrate
g. Daclatasvir hydrochloride/asunaprevir/beclabuvir hydrochloride
h. Glecaprevir hydrate/pibrentasvir
i. Sofosbuvir/velpatasvir

Branded name (Marketing authorization holder)

a. Daklinza Tablets 60 mg (Bristol-Myers Squibb Company)
b. Sunvepra Capsules 100 mg (Bristol-Myers Squibb Company)
c. Sovaldi Tablets 400 mg (Gilead Sciences Inc.)
d. Harvoni Combination Tablets (Gilead Sciences Inc.)
e. Erelsa Tablets 50 mg (MSD K.K.)
f. Grazyna Tablets 50 mg (MSD K.K.)
g. Ximency Combination Tablets (Bristol-Myers Squibb Company)
h. Maviret Combination Tablets (AbbVie GK)
i. Epclusa Combination Tablets (Gilead Sciences Inc.

Pharmaceuticals and Medical Devices Agency

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Indications

a., b., e. to g.

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

c.

Improvement of viremia in chronic hepatitis C or compensated cirrhosis C of any of the following types

1) Patients with serogroup 2 (genotype 2)
2) Patients with neither serogroup 1 (genotype 1) nor serogroup 2 (genotype 2)

d.

Improvement of viremia in patients with serogroup 1 (genotype 1) or serogroup 2 (genotype 2) chronic hepatitis C or compensated cirrhosis C

h.

Improvement of viremia in patients with chronic hepatitis C or compensated cirrhosis C

i.

Improvement of viremia in patients with previously treated chronic hepatitis C or compensated cirrhosis C

Improvement of viremia in patients with decompensated cirrhosis C

Summary of revisions

Language concerning dose adjustment that may be required for currently administered drugs currently administered (warfarin, tacrolimus or other drugs with a narrow therapeutic windows that are metabolized by the liver, or anti-diabetic agents) should be added to the Important Precautions section as a precaution when initiating this drug in patients receiving such drugs.

Investigation results and background of the revision

Several studies have reported* that dose adjustment may be required for co-administered drugs such as warfarin, tacrolimus, and insulin following initiation of direct-acting antivirals for chronic hepatitis C or compensated/decompensated cirrhosis C. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.

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Number of cases and patient mortalities reported in Japan during the previous 3 fiscal years

N/A

*An investigation using MID-NET® has been conducted associated with the consideration for the current revision.

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

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