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Summary of Investigation Results

Eplerenone Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate Darunavir ethanolate/cobicistat Darunavir ethanolate/cobicistat/emtricitabine/tenofovir alafenamide fumarate

March 17, 2026

Non-proprietary name

- a. Eplerenone
- b. Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide fumarate
- c. Darunavir ethanolate/cobicistat
- d. Darunavir ethanolate/cobicistat/emtricitabine/tenofovir alafenamide fumarate

Brand name (marketing authorization holder)

- a. Selara Tablets 25 mg, 50 mg, 100 mg (Viatris Pharmaceuticals Japan G.K.), and others
- b. Genvoya Combination Tablets (Gilead Sciences K.K.)
- c. Prezcofix Combination Tablets (Janssen Pharmaceutical K.K.)
- d. Symtuza Combination Tablets (Janssen Pharmaceutical K.K.)

Japanese market launch

- a. November 2007
- b. July 2016
- c. January 2017
- d. July 2019

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Indications

a.

<Selara Tablets 25 mg, 50 mg, and 100 mg>

Hypertension

<Selara Tablets 25 mg, 50 mg>

Patients with the following disease who are receiving basic treatment with angiotensin-converting enzyme inhibitors or angiotensin II receptor antagonists, β -blockers, diuretics, etc.:

Chronic heart failure

b., d. HIV-1 infection

c. HIV infection

Summary of revisions

a.

1. "Preparations containing cobicistat" should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)
2. "Preparations containing cobicistat (Genvoya, Prezcofix, and Symtuza)" should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

b., c., d.

1. "Eplerenone" should be added to 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.)
2. "Eplerenone (Selara)" should be added to the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.

Investigation results and background of the revision

Pharmacokinetic effects and post-marketing safety information regarding the co-administration of eplerenone with preparations containing cobicistat were evaluated. As a result of consultation with expert advisors, the MHLW/PMDA concluded that revising PRECAUTIONS to contraindicate co-administration of these drugs was necessary for the following reasons:

- In the clinical drug-drug interaction studies in which ketoconazole, a strong CYP3A inhibitor, was co-administered, the exposure of eplerenone (AUC) increased by

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approximately 5.4-fold. Taking this into account, drugs with a strong CYP3A inhibitory activity comparable to that of ketoconazole (such as itraconazole) have been contraindicated for co-administration since the marketing approval of eplerenone.

- There are no results of clinical drug-drug interaction studies of eplerenone with preparations containing cobicistat. However, it is known that cobicistat strongly inhibits CYP3A. When eplerenone is co-administered with these drugs, there is a concern that the blood concentration of eplerenone markedly increases, and the risk of adverse reactions increases.

Of note, opinions regarding the impacts of contraindicating co-administration of eplerenone with preparations containing cobicistat in clinical settings were sought from relevant academic societies, which confirmed that there were no specific problems.

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).

Pharmaceuticals and Medical Devices Agency

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