

For Immediate Release

August 28, 2019
Sawai Pharmaceutical Co., Ltd.

**MHLW Approves Additional Indications for
CANDESARTAN Tablets and OD Tablets**

Osaka, Japan – August 28, 2019 – Sawai Pharmaceutical Co., Ltd. (Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of its partial change application by the Ministry of Health, Labour and Welfare (MHLW) for CANDESARTAN Tablets 2 mg, 4 mg, 8 mg and 12 mg [SAWAI], and CANDESARTAN OD Tablets 2 mg, 4 mg, 8 mg and 12 mg [SAWAI]*.

This approval expands the indications of CANDESARTAN products to include the same uses as their brand equivalents.

* Brand products: BLOPRESS® (Candesartan Cilexetil) Tablets 2 mg, 4 mg, 8 mg and 12 mg

“Indications and Usage” and “Dosage and Administration” after approval are described below (New approval is underlined);

Indications and Usage

Tablets 2 mg, 4 mg, 8 mg and 12 mg, and OD Tablets 2 mg, 4 mg, 8 mg and 12 mg

1. Hypertension

2. Renal parenchymal hypertension

Tablets 2 mg, 4 mg, and 8 mg, and OD Tablets 2 mg, 4 mg, and 8 mg

3. Chronic cardiac failure (mild to moderate) for which administration of angiotensin converting enzyme inhibitors is not appropriate

Dosage and Administration

Tablets 2 mg, 4 mg, 8 mg and 12 mg, and OD Tablets 2 mg, 4 mg, 8 mg and 12 mg

1. Hypertension

Adults

The usual adult dose for oral use is 4 to 8 mg of candesartan cilexetil once daily, increased to 12 mg if necessary. The initial dose for patients with hypertension associated with renal impairment is 2 mg once daily, increased to 8 mg if necessary.

Children

The usual dose for children ≥ 1 year and < 6 years of age is 0.05 to 0.3 mg/kg as candesartan cilexetil orally administered once daily.

The usual dose for children ≥ 6 years of age is 2 to 8 mg as candesartan cilexetil orally administered once daily, increased to 12 mg if necessary. Start with a low dose for patients with hypertension associated with renal impairment and increase the dose to 8 mg if necessary.

2. Renal parenchymal hypertension

The usual initial adult dose for oral use is 2 mg of candesartan cilexetil once daily, increased to 8 mg if necessary.

Tablets 2 mg, 4 mg, and 8 mg, and OD Tablets 2 mg, 4 mg, and 8 mg

3. Chronic cardiac failure (mild to moderate) for which administration of angiotensin converting enzyme inhibitors is not appropriate

The usual adult dose for oral use is 4 mg of candesartan cilexetil once daily, increased to 8 mg if necessary. In principle, background therapy other than angiotensin converting enzyme inhibitors should be continued.

The products announced in this press release are not approved by the Food & Drug Administration for sale and distribution in the United States.

◆ Contact information ◆

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