

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.

About Sawai

Founded in 1929, Sawai Pharmaceutical Co., Ltd. has grown into one of the leading generics companies in Japan. Guided by its corporate philosophy, "Always Putting Patients First," Sawai markets more than 310 high-quality generic drugs with 760 strengths and reliably delivers them to patients throughout Japan. In 2017, Sawai acquired US-based Upsher-Smith Laboratories, LLC marking its first step in overseas expansion to become a globally recognized generic pharmaceutical company. For more information, visit: <https://www.sawai.co.jp/en/>.

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