For Immediate Release

March 27, 2019
Sawai Pharmaceutical Co., Ltd.

MHLW Approves New Indication for DONEPEZIL Tablets, OD Tablets and Fine Granules

Osaka, Japan – March 27, 2019 – Sawai Pharmaceutical Co., Ltd. (Sawai, Head office: Osaka, Japan, President: Mitsuo Sawai) today received approval of partial change applications by the Ministry of Health, Labour and Welfare (MHLW) for DONEPEZIL HYDROCHLORIDE Tablets 3 mg, 5 mg and 10 mg [SAWAI], DONEPEZIL HYDROCHLORIDE OD Tablets 3 mg, 5 mg and 10 mg [SAWAI], and DONEPEZIL HYDROCHLORIDE Fine Granules 0.5 % [SAWAI]*.
This approval expands the indication of DONEPEZIL HYDROCHLORIDE products to include the same uses as their brand equivalents.

* Brand products: Aricept® Tablets 3 mg, 5 mg and 10mg, Aricept® D Tablets 3 mg, 5mg and 10 mg, Aricept® Fine Granules 0.5 %

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

Indications and Usage

1. Suppression of progression of dementia symptoms in dementia of the Alzheimer's type
2. Suppression of progression of dementia symptoms in dementia with Lewy bodies

Dosage and Administration

1. Suppression of progression of dementia symptoms in dementia of the Alzheimer's type
   The usual initial adult dose for oral use is 3 mg of donepezil hydrochloride once daily. After 1 to 2 weeks the dose is increased to 5 mg. The dosage for patients with severe dementia of the Alzheimer's type is increased to 10 mg after dosing at 5 mg for 4 or more weeks. The dose can be reduced appropriately according to patients' symptoms.
2. Suppression of progression of dementia symptoms in dementia with Lewy bodies
   The usual initial adult dose for oral use is 3 mg of donepezil hydrochloride once daily. After 1 to 2 weeks the dose is increased to 5 mg. The dose is increased to 10 mg after dosing at 5 mg for 4 or more weeks. The dose can be reduced to 5 mg according to patients' symptoms.

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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