

May 17, 2023

To whom it may concern:

Company Name Corporate Representative	TOHO HOLDINGS CO., LTD. Atsushi Udoh, Representative Director, CEO (Prime Market of Tokyo Stock Exchange Securities Code: 8129)
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Notice Regarding Approval of Partial Amendments to Dosage and Administration of
Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD Tablets
3mg / 5mg / 10mg “FFP” for KYOSOMIRAI PHARMA

TOHO HOLDINGS CO., LTD. (Headquarters: Tokyo; Representative Director, CEO: Atsushi Udoh) is pleased to announce that KYOSOMIRAI PHARMA CO., LTD. (Headquarters:Tokyo; President and Representative Director: Nobuaki Hosaka), the wholly-owned subsidiary involved in pharmaceuticals manufacture and sales business, received an approval of partial amendments to dosage and administration of Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD Tablets 3mg / 5mg / 10mg “FFP” on May 17, 2023 as below.

Outline of Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD Tablets 3mg / 5mg / 10mg “FFP”

Class	Product Name	Original Brand Name
Therapeutic agent for Alzheimer's disease Therapeutic agent for dementia with Lewy bodies	Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP”	Aricept [®] Tablets 3mg/ 5mg/ 10mg
	Donepezil Hydrochloride OD Tablets 3mg / 5mg / 10mg “FFP”	Aricept [®] D Tablets 3mg/ 5mg/ 10mg

Outline of Amendments to Dosage and Administration of Donepezil Hydrochloride Tablets 3mg / 5mg / 10mg “FFP” and Donepezil Hydrochloride OD Tablets 3mg / 5mg / 10mg “FFP”

Indications and Usage	Suppression of progression of dementia symptoms in Alzheimer's disease and dementia with Lewy bodies
Dosage and Administration	<p>Suppression of progression of dementia symptoms in Alzheimer's disease The usual initial adult dose for oral use is 3mg of donepezil hydrochloride once daily. After 1 to 2weeks the dose is increased to 5mg. The dosage for patients with severe Alzheimer's disease is increased to 10mg after dosing at 5mg for 4 or more weeks. The dose can be reduced appropriately according to patients' symptoms.</p> <p>Suppression of progression of dementia with Lewy bodies The usual initial adult dose for oral use is 3mg of donepezil hydrochloride once daily. After 1 to 2weeks the dose is increased to 5mg. The dosage for patients with severe Alzheimer's disease is increased to 10mg after dosing at 5mg for 4 or more weeks. The dose can be reduced to 5mg according to patients' symptoms. <u>By approximately 12 weeks after the start of administration of the drug, perform an efficacy evaluation based on a cognitive function test and a hearing with the patient and his/her family and/or caregiver on the subjective/objective symptoms, and if the benefits shown in the comprehensive evaluation of cognitive function, psychological symptoms, behavior disturbance, activities on daily living, etc. are not considered to outweigh the risk, discontinue the administration. Even if the administration is continued based on the result of efficacy evaluation by 12 weeks after the start of administration, regularly perform an efficacy evaluation to determine whether or not to continue the administration.</u></p>

(Underlined parts are revised parts.)