

June 16, 2021

To whom it may concern:

Company Name Corporate Representative	TOHO HOLDINGS CO., LTD. Atsushi Udoh, President and Representative Director (First Section of Tokyo Stock Exchange Securities Code:8129)
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Notice Regarding Approval of Partial Amendments to Indications, Dosage and Administration of DULOXETINE Capsules 20mg/30mg “KMP” for KYOSOMIRAI PHARMA

TOHO HOLDINGS CO., LTD. (Headquarters: Tokyo; President and Representative Director: 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 indications, dosage and administration of DULOXETINE Capsules 20mg/30mg “KMP” on June 16, 2021 as below.

DULOXETINE Capsules 20mg/30mg “KMP”, for which KYOSOMIRAI PHARMA CO., LTD. obtained marketing approval on February 15, 2021, is in the process of being listed in the National Health Insurance drug price list. With the approval of partial amendments, the said product can be used with the same indications, dosage and administration as the brand-name product after market launch.

Outline of DULOXETINE Capsules 20mg/30mg “KMP”

Classes	Product Name	Original Brand Name
Serotonin-norepinephrine reuptake inhibitors	DULOXETINE Capsules 20mg/30mg “KMP”	Cymbalta® Capsules 20mg/30mg

Outline of Amendments to Indications, Dosage and Administration of DULOXETINE Capsules 20mg/30mg “KMP”

Indications and Usage	<ul style="list-style-type: none"> ○ Depression and depressed state ○ Pains associated with the following conditions <ul style="list-style-type: none"> Diabetic neuropathy Fibromyalgia <u>Chronic lumbago</u> <u>Osteoarthritis</u>
Dosage and Administration	<p><Depression/depressed state and pain associated with diabetic neuropathy> The usual dosage in adults is 40mg as duloxetine orally taken once daily after breakfast. Start at 20mg/day, and allow at least 1 week before increasing the dose by 20mg/day. If the response is inadequate, the dose may be increased up to 60mg/day.</p> <p><Pains associated with fibromyalgia, <u>Chronic lumbago</u>, and <u>osteoarthritis</u>> The usual dosage in adults is 60mg as duloxetine orally taken once daily after breakfast. Start at 20mg/day, and allow at least 1 week before increasing the dose by 20mg/day.</p>

(Underlined parts are revised parts.)