



Summary of investigation results

Duloxetine hydrochloride

April 23, 2015

Non-proprietary name

duloxetine hydrochloride

Brand name (Marketing authorization holder)

Cymbalta Capsules 20 mg and 30 mg (Shionogi & Co., Ltd)

Indications

1. Depression/depressed state
2. Diabetic peripheral neuropathic pain

Summary of revision

‘Neuroleptic malignant syndrome’ should be added to the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of neuroleptic malignant syndrome have been reported in patients treated with duloxetine hydrochloride in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 5 cases of neuroleptic malignant syndrome has been reported (including 3 cases in which causality could not be ruled out). Of the 5 cases, no fatality has been reported.