This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Paroxetine hydrochloride hydrate

July 8, 2014

Non-proprietary Name

Paroxetine hydrochloride hydrate

Brand Name (Marketing Authorization Holder)

a. Paxil tablets 5 mg, 10 mg, and 20 mg (GlaxoSmithKline K.K.), and the others
b. Paxil CR tablets 12.5 mg, and 25 mg (GlaxoSmithKline K.K.)

Indications

a. Depression/depressed state, panic disorder, obsessive-compulsive disorder, social anxiety disorder, and post-traumatic stress disorder
b. Depression/depressed state

Summary of revision

Anaphylaxis should be added in Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of anaphylaxis have been reported in patients treated with paroxetine in Japan and foreign countries and a company core data sheet (CCDS)* has been updated. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

A total of 3 anaphylaxis-associated cases has been reported (no case in which causality could not be ruled out). Of the 3 cases, no fatalities have been reported.

NOTE
*CCDS is prepared by a marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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