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

Summary of investigation results Risperidone (injections), Paliperidone palmitate

March 22, 2016

Non-proprietary name

a. Risperidone (injections)

b. Paliperidone palmitate

Brand name (Marketing authorization holder)

a. Risperdal Consta Intramuscular Injection 25 mg, 37.5 mg, 50 mg (Janssen Pharmaceutical K.K.)

b. Xeplion Aqueous Suspension for IM Injection 25 mg, 50 mg, 75 mg, 100 mg, 150 mg (Janssen Pharmaceutical K.K.)

Indications

Schizophrenia

Summary of revision

“Anaphylaxis” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of anaphylaxis have been reported in patients treated with risperidone (injections) and paliperidone palmitate both in Japan and overseas. In addition, the company core datasheet (CCDS)* and the Summary of product characteristics in Europe have been updated. 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.

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

a. A case of anaphylaxis has been reported (a causal relationship to the product could not be ruled out for this patient). No fatality has been reported.

b. A total of 3 cases associated with anaphylaxis have been reported (including a case for which a causal relationship to the product could not be ruled out). Of the 3 cases, 2 fatal cases have been reported (a causal relationship between the product and the fatal outcome could not be established for these patients).

NOTE:

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

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