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Pharmaceuticals and Medical Devices Agency

Summary of Investigation Results Clozapine

March 19, 2019

Non-proprietary name

Clozapine

Branded name (Marketing authorization holder)

Clozaril Tablets 25 mg, 100 mg (Novartis Pharma K.K.)

Indications Treatment-resistant schizophrenia

Summary of revisions

"Intestinal ulcer, intestinal perforation" should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of intestinal ulcer have been reported overseas, and cases of intestinal perforation have been reported in Japan and overseas both in patients treated with clozapine. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

No cases involving intestinal ulcer have been reported to date.

A total of 4 cases involving intestinal perforation have been reported to date (a causal relationship with the product could not be established in these cases.) No patient mortalities have been reported to date.

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