



Summary of investigation results

Clozapine

November 28, 2017

Non-proprietary name

Clozapine

Brand name (Marketing authorization holder)

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

Indication

Treatment-resistant schizophrenia

Summary of revision

"Pleurisy" should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of pleurisy have been reported in patients treated with clozapine in Japan and overseas, and the company core data sheet (CCDS) has been revised. Following investigation results 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 6 cases associated with pleurisy have been reported (including a case for which a causal relationship to the product could not be ruled out). No fatality has been reported.