



# 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.