



# Summary of investigation results

## Iguratimod

January 10, 2017

### Non-proprietary name

Iguratimod

### Brand name (Marketing authorization holder)

Careram Tablets 25 mg (Eisai Co., Ltd.), Kolbet Tablets 25 mg (Toyama Chemical Co., Ltd.)

### Indications

Rheumatoid arthritis

### Summary of revision

“Agranulocytosis” should be added to the “pancytopenia and leukopenia” subsection in the Clinically Significant Adverse Reactions section.

### Background of the revision and investigation results

Cases of agranulocytosis have been reported in patients treated with iguratimod in Japan. 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.

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

A total of 10 cases associated with agranulocytosis have been reported (including 9 cases for which a causal relationship to the product could not be ruled out). No fatality has been reported.