



# Summary of investigation results

## Polaprezinc

November 22, 2016

### Non-proprietary name

Polaprezinc

### Brand name (Marketing authorization holder)

Promac Granules 15 %, Promac D Tablets 75 mg (ZERIA Pharmaceutical Co., Ltd.), and the others

### Indications

Gastric ulcer

### Summary of revision

“Copper deficiency” should be newly added in the Clinically Significant Adverse Reactions section.

### Background of the revision and investigation results

Cases of copper deficiency have been reported in patients treated with polaprezinc 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 9 cases associated with copper deficiency have been reported (including 8 cases for which a causal relationship to the product could not be ruled out; however, 4 of these 8 cases used the drug for a condition that was not included in the approved indication). No fatality has yet been reported.