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# Summary of investigation results

## Eltrombopag olamine

September 13, 2016

**Non-proprietary name**

Eltrombopag olamine

**Brand name (Marketing authorization holder)**

Revolade Tablets 12.5 mg, 25 mg (Novartis Pharma K.K.)

**Indications**

Chronic idiopathic thrombocytopenic purpura

**Summary of revision**

The description on the administration interval between this drug and products such as antacids, milk products, and formulations containing multivalent cations (iron, calcium, aluminum, magnesium, selenium, zinc etc.) should be revised in Precautions of dosage and administration section.

**Background of the revision and investigation results**

The company core datasheet (CCDS)* has been updated based on the results of foreign clinical pharmacokinetic studies. 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**

N/A

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Note:

*CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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