This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Deferasirox

August 6, 2015

Non-proprietary name

Deferasirox

Brand name (Marketing authorization holder)

Exjade Dispersible Tablets 125 mg and 500 mg (Novartis Pharma K.K.)

Indications

Chronic iron overload due to blood transfusions (cases when injection of iron chelating agent is inadequate)

Summary of revision

"Gastrointestinal perforations" should be added to the gastric ulcer (including multiple ulcers), duodenal ulcer, and gastrointestinal haemorrhage subsection in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of gastrointestinal perforations have been reported in patients treated with deferasirox both in Japan and overseas. In addition, the company core datasheet (CCDS)* has been updated. 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

No case associated with gastrointestinal perforations has been reported.

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NOTE:

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

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