



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

Revision of Precautions

Deferasirox

August 6, 2015

Non-proprietary name

Deferasirox

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection regarding gastric ulcer, duodenal ulcer, and gastrointestinal haemorrhage of the Adverse reactions section, the following text should be revised (underlined parts are revised):

Gastrointestinal perforations, gastric ulcers (including multiple ulcers), duodenal ulcers, and gastrointestinal haemorrhage:

Gastrointestinal perforations, gastric ulcers (including multiple ulcers), duodenal ulcers, or gastrointestinal haemorrhage may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as drug suspension should be adopted.