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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 Polaprezinc

November 22, 2016

Non-proprietary name

Polaprezinc

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Copper deficiency:

Copper deficiency may occur because polaprezinc contains zinc, which inhibit the absorption of copper. Pancytopenia and anaemia associated with copper deficiency have been reported in poorly nourished patients. If any abnormalities are observed, appropriate measures should be adopted.

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