This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

Attachment 3

June 16, 2026

【Therapeutic category】 Mineral preparations

【Non-proprietary name】Saccharated ferric oxide

【Safety measure】PRECAUTIONS should be revised.

A revised description is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS N/A	8. IMPORTANT PRECAUTIONS Hypophosphataemia may occur and lead to osteomalacia in patients treated with this drug. Serum phosphorus levels should be measured prior to treatment with this drug unless there are unavoidable circumstances. In addition, serum phosphorus levels should be measured periodically even during treatment, and phosphorus replacement should be considered as necessary. Patients should be instructed to consult a prescribing physician if symptoms suggestive of osteomalacia, such as arthralgia and bone pain occur.
11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactions Osteomalacia Long-term treatment may cause osteomalacia accompanied by bone pain, arthralgia, etc.	11. ADVERSE REACTIONS 11.1 Clinically Significant Adverse Reactionsc Hypophosphataemia, osteomalacia Hypophosphataemia may occur and lead to osteomalacia.

N/A: Not Applicable. No corresponding description is included in the current PRECAUTIONS.

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.