Published by Ministry of Health, Labour and Welfare



Translated by Pharmaceuticals and Medical Devices Agency



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 Hydroxocobalamin

July 4, 2017

## Non-proprietary name

Hydroxocobalamin

## 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):

Acute kidney injury:

Acute kidney injury may occur, and cases with renal tubular necrosis have also been reported. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures should be taken.

Pharmaceuticals and Medical Devices Agency Office of Safety I 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u>