



Summary of investigation results

Hydroxocobalamin

July 4, 2017

Non-proprietary name

Hydroxocobalamin

Brand name (Marketing authorization holder)

Cyanokit for Injection 5 g Set (Merck Serono Co., Ltd.)

Indications

Cyanogen and cyanide poisoning

Summary of revision

“Acute kidney injury” should be newly added in the Clinically Significant Adverse Reactions section.

Background of the revision and investigation results

Cases of acute kidney injury have been reported in patients treated with hydroxocobalamin both in Japan and overseas, and the company core data sheet (CCDS) has been revised. Following investigation results 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

A total of 2 cases associated with acute kidney injury have been reported (including no case for which a causal relationship to the product could not be ruled out). No fatality has been reported.