



Summary of Investigation Results

Calcitriol (injectable dosage form)

November 27, 2018

Non-proprietary name

Calcitriol (injectable dosage form)

Branded name (Marketing authorization holder)

Rocaltrol Injection 0.5, 1 (Kyowa Hakko Kirin Co., Inc.), and the others

Indications

Secondary hyperparathyroidism in patients undergoing maintenance dialysis

Summary of revisions

“Shock, anaphylaxis” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of shock or anaphylaxis have been reported in patients treated with calcitriol (injectable dosage form) in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 4 cases involving shock or anaphylaxis have been reported to date (including 1 case for which a causal relationship with the product could not be ruled out.)

No patient mortalities have been reported to date.