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Pharmaceuticals and Medical Devices Agency

## 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.

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