



Summary of investigation results

Amantadine hydrochloride

September 15, 2015

Non-proprietary name

Amantadine hydrochloride

Brand name (Marketing authorization holder)

Symmetrel Tablets 50 mg and 100 mg, Symmetrel Fine Granules 10% and the others
(Novartis Pharma K.K. and others)

Indications

Parkinson's syndrome; Improvement of hypobulia or decreased initiative associated with sequela of cerebral infarction; Type A influenza virus infection

Summary of revision

"Rhabdomyolysis" should be newly added in the Clinically significant adverse reactions section.

Background of the revision and investigation results

Cases of rhabdomyolysis have been reported in patients treated with amantadine hydrochloride in Japan. Following an investigation result 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 case associated with rhabdomyolysis has been reported (a causal relationship to the product could not be ruled out for this patient). The one reported case did not have a fatal outcome.