



Summary of investigation results

Oseltamivir phosphate

April 21, 2016

Non-proprietary name

Oseltamivir phosphate

Brand name (Marketing authorization holder)

Tamiflu Capsules 75, Tamiflu Dry Syrup 3% (Chugai Pharmaceutical Co., Ltd.)

Indications

Type A or B influenza virus infection and its prophylaxis

Summary of revision

“Ischaemic colitis” should be newly added to the “haemorrhagic colitis” subsection in the “Clinically significant adverse reaction” section.

Background of the revision and investigation results

Cases of ischaemic colitis have been reported in patients treated with oseltamivir phosphate 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 total of 4 cases associated with ischaemic colitis have been reported (including 1 case for which a causal relationship to the product could not be ruled out). No fatality has been reported.