



Summary of Investigation Results

Baloxavir marboxil

June 4, 2019

Non-proprietary name

Baloxavir marboxil

Branded name (Marketing authorization holder)

Xofluza Tablets 10 mg, 20 mg, Xofluza granule 2% portions (Shionogi & Co., Ltd.)

Indications

Influenza A or B viral infections

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 baloxavir marboxil 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 cases and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 42 cases involving shock or anaphylaxis have been reported to date (including 16 cases for which a causal relationship between the drug and event could not be ruled out.)
1 instance of patient mortality has been reported to date (a causal relationship between the drug and the death subsequent to event could not be established in this case.)