



This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of Precautions

Baloxavir marboxil

August 21, 2018

Non-proprietary name

Baloxavir marboxil

Safety measure

Precautions should be revised in the package insert.

The language concerning neuropsychiatric symptoms including abnormal behaviour should be revised as follows in the Important Precautions section (revised language is underlined):

Abnormal behaviour has been reported in patients infected with influenza, regardless of the use or non-use, or the type of influenza antiviral drug prescribed.

Patients and/or their families must be made aware of the following precautionary points to avoid rare accidents including falls due to abnormal behaviour; (1) abnormal behaviour may occur and (2) caregivers should take preventive measures for accidents including falls for at least 2 days after patients develop pyrexia if they are treated at home.

Severe abnormal behaviour potentially leading to accidents such as falls is known to have been reported to occur with greater frequency in male school-age children/adolescents, and within 2 days after patients develop pyrexia.

Published by
Ministry of Health, Labour and Welfare



Translated by
Pharmaceuticals and Medical Devices Agency



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A Clinically Significant Adverse Reactions subsection should be newly added and the following language should be included in the Adverse Reaction section (revised language is underlined):

Abnormal behaviour:

Abnormal behaviour (such as sudden movement or wandering) that could result in falls etc. may occur in patients infected with influenza, although the existence of a causal relationship between these symptoms and this drug is currently unclear.

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