



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

Oseltamivir phosphate

August 21, 2018

Non-proprietary name

Oseltamivir phosphate

Safety measure

Precautions should be revised in the package insert.

The following language should be deleted from the Warnings section:

Abnormal behaviour that has resulted in accidents such as falls has been reported in patients aged 10 to 19 years following administration of this drug, although the existence of a causal relationship between these symptoms and this drug is currently unclear. As a general rule, this drug should not be used in patients in this age group for the above reason except when the patient is considered at higher risk based on complications and past history, etc.

When this drug is administered to children/adolescents, patients and/or their families must be made aware of the following precautionary points to avoid rare accidents that, after initiation of treatment with this drug; (1) abnormal behaviour may occur and (2) caregivers should be careful not to leave child/adolescent patients alone for at least 2 days if they are treated at home.

It has also been reported that similar symptoms occur due to influenza encephalopathy, and patients and/or their families must be made aware of the same as above.



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The following language should be added to 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 at least for 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.

The language concerning neuropsychiatric symptoms should be revised as follows in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Neuropsychiatric symptoms, abnormal behaviour:

Neuropsychiatric symptoms (such as disturbed consciousness, delirium, hallucination, delusion, and convulsion) may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken according to the patient's symptoms. 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.