



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

Amantadine hydrochloride

August 21, 2018

Non-proprietary name

Amantadine hydrochloride

Safety measure

Precautions should be revised in the package insert.

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

Use of this drug for "Influenza A virus infection"

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.

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The language concerning disturbed consciousness, psychiatric symptoms, convulsions, and myoclonus should be revised as follows in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, (revised language is underlined):

Disturbed consciousness (including coma), psychiatric symptoms (such as hallucination, delusion, delirium, and confusion), convulsions, myoclonus, and abnormal behaviour:

Disturbed consciousness (including coma), psychiatric symptoms (such as hallucination, delusion, delirium, and confusion), convulsions, myoclonus may occur. In such cases, appropriate measures including reducing the dosage or discontinuing administration should be taken. Caution should be exercised as these symptoms may occur with particular frequency in patients exhibiting decreased renal function. 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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