



*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

March 1, 2019

### **Non-proprietary name**

Baloxavir marboxil

### **Safety measure**

Precautions should be revised in the package insert.

The following language should be added to the Important Precautions section (revised language is underlined):

Bleeding may occur. Patients and their families should be informed that:

- 1) The attending physician should be contacted if bloody stool, epistaxis, haematuria, or other forms of bleeding are observed.
- 2) These symptoms may appear several days after administration of this drug.

An Interactions section should be newly added and the following language should be included in the Precautions for Co-administration subsection (revised language is underlined):

Warfarin

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The following language should be added to the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Bleeding:

Bloody stool, epistaxis, haematuria, or other forms of bleeding may occur. Appropriate measures should be taken if these symptoms appear.

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