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Translated by
Pharmaceuticals and Medical Devices Agency



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 31, 2020

Therapeutic category

Antivirals

Non-proprietary name

Baloxavir marboxil

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

| Current | Revision |
|--|--|
| Adverse Reactions Clinically Significant Adverse Reactions (N/A) | Adverse Reactions Clinically Significant Adverse Reactions <u>Ischaemic colitis:</u> <u>Ischaemic colitis may occur. If abnormalities such as abdominal pain, diarrhoea, and bloody stool are observed, appropriate measures should be taken.</u> |

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

| Current | Revision |
|--|--|
| 11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions (N/A) | 11. ADVERSE REACTIONS 11.1. Clinically Significant Adverse Reactions <u>Ischaemic colitis</u> <u>If abnormalities such as abdominal pain, diarrhoea, and bloody stool are observed, appropriate measures should be taken.</u> |

N/A: Not Applicable, because the section is not included in the current package insert.

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