

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate

March 17, 2026

Therapeutic category

Anti-virus agents

Non-proprietary name

Bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate

Safety measure

PRECAUTIONS should be revised.

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Revised language is underlined.

| Current | | | Revision | | |
|--|---|--|--|---|--|
| 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients receiving the following drugs: Rifampicin, carbamazepine, phenobarbital, phenytoin, fosphenytoin, food containing St. John's Wort | | | 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Patients receiving the following drugs: Rifampicin, carbamazepine, phenobarbital, phenytoin, fosphenytoin, <u>apalutamide</u> , food containing St. John's Wort, <u>enzalutamide</u> | | |
| 10. INTERACTIONS 10.1 Contraindications for Co-administration (Do not co-administer with the following.) | | | 10. INTERACTIONS 10.1 Contraindications for Co-administration (Do not co-administer with the following.) | | |
| Drugs | Signs, symptoms, and treatment | Mechanism/risk factors | Drugs | Signs, symptoms, and treatment | Mechanism/risk factors |
| Carbamazepine Phenobarbital Phenytoin Fosphenytoin Food containing St. John's Wort | Since the plasma concentration of bictegravir and tenofovir alafenamide decreases, the effects of this drug may be attenuated, and resistance to this drug may occur. | It is considered that these drugs induce CYP3A and P-gp. | Carbamazepine Phenobarbital Phenytoin Fosphenytoin <u>Apalutamide</u> Food containing St. John's Wort | Since the plasma concentration of bictegravir and tenofovir alafenamide decreases, the effects of this drug may be attenuated, and resistance to this drug may occur. | It is considered that these drugs induce CYP3A and P-gp. |

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| (N/A) | Drugs | Signs, symptoms, and treatment | Mechanism/risk factors |
|-------|---------------------|--|--|
| | <u>Enzalutamide</u> | <u>Since the plasma concentration of bicitgravir decreases, the effects of this drug may be attenuated, and resistance to this drug may occur.</u> | <u>It is considered that enzalutamide induces CYP3A.</u> |

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.