

*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.*

Attachment 12  
July 14, 2026

【Therapeutic category】 619 Other antibiotic preparations

【Non-proprietary name】 Vonoprazan fumarate/amoxicillin hydrate/clarithromycin

Vonoprazan fumarate/amoxicillin hydrate/metronidazole

【Safety measure】 PRECAUTIONS should be revised.

A revised description is underlined.

| Current                                                                                                    | Revision                                                                                                                                                                                                                                                                                                                                                                                          |
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| 8. IMPORTANT PRECAUTIONS<br>< Vonoprazan fumarate ><br>(N/A)                                               | 8. IMPORTANT PRECAUTIONS<br>< Vonoprazan fumarate ><br><u>Prolonged use of proton pump inhibitors may cause hypomagnesaemia.</u><br><u>Blood magnesium levels should be periodically measured when long-term treatment with proton pump inhibitors is deemed necessary.</u>                                                                                                                       |
| 11. ADVERSE REACTIONS<br>11.1 Clinically Significant Adverse Reactions<br>< Vonoprazan fumarate ><br>(N/A) | 11. ADVERSE REACTIONS<br>11.1 Clinically Significant Adverse Reactions<br>< Vonoprazan fumarate ><br><u>Hypomagnesaemia</u><br><u>Prolonged use of proton pump inhibitors may cause hypomagnesaemia accompanied by symptoms such as prolonged QT, convulsion, and numbness. Electrolyte abnormalities such as hypocalcaemia and hypokalaemia caused by hypomagnesaemia may also occur. If any</u> |

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|  | <u>symptoms suggestive of these electrolyte abnormalities occur, blood magnesium levels should be measured. If any abnormality is observed, appropriate measures should be taken such as magnesium replacement.</u> |
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N/A: Not Applicable. No corresponding description is included in the current PRECAUTIONS.

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