Revision of PRECAUTIONS

Dabigatran etexilate methanesulfonate

August 29, 2023

Therapeutic category
Anticoagulants

Non-proprietary name
Dabigatran etexilate methanesulfonate

Safety measure
PRECAUTIONS should be revised.
Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

<table>
<thead>
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<th>Current</th>
<th>Revision</th>
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| **8. IMPORTANT PRECAUTIONS**  
(N/A) | **8. IMPORTANT PRECAUTIONS**  
If this drug is retained in the esophagus, oesophageal ulcer or oesophagitis may occur. Patients should be instructed as follows:  
• This drug should be taken with a sufficient amount (e.g., a full glass) of water to facilitate delivery to the stomach.  
• If symptoms of oesophageal disease (difficult swallowing or odynophagia, retrosternal pain, severe and persistent heartburn, etc.) occur, the attending physician should be consulted. |
| **11. ADVERSE REACTIONS**  
11.1 Clinically Significant Adverse Reactions  
(N/A) | **11. ADVERSE REACTIONS**  
11.1 Clinically Significant Adverse Reactions  
Oesophageal ulcer, oesophagitis |
| **14. PRECAUTIONS CONCERNING USE**  
Precautions Concerning Administration of the Drug  
This drug should be taken with a sufficient amount (e.g., a full glass) of water to facilitate delivery to the stomach. | **14. PRECAUTIONS CONCERNING USE**  
Precautions Concerning Administration of the Drug  
(deleted) |

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