Revision of PRECAUTIONS

Nintedanib ethanesulfonate, Axitinib, Aflibercept beta (genetical recombination), Cabozantinib malate, Sunitinib malate, Sorafenib tosilate, Pazopanib hydrochloride, Vandetanib, Ponatinib hydrochloride, Ramucirumab (genetical recombination), Regorafenib hydrate, Lenvatinib mesilate

February 15, 2024

Therapeutic category
Agents affecting metabolism, n.e.c. (not elsewhere classified)
Other antitumor agents
Non-proprietary name
Nintedanib ethanesulfonate
Axitinib
Aflibercept beta (genetical recombination)
Cabozantinib malate
Sunitinib malate
Sorafenib tosilate
Pazopanib hydrochloride
Vandetanib
Ponatinib hydrochloride
Ramucirumab (genetical recombination)
Regorafenib hydrate
Lenvatinib mesilate

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>
<tr>
<th>Current</th>
<th>Revision</th>
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<tbody>
<tr>
<td>11. ADVERSE REACTIONS</td>
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<tr>
<td>11.1 Clinically Significant Adverse Reactions (N/A)</td>
<td>11.1 Clinically Significant Adverse Reactions</td>
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<tr>
<td>Artery dissection</td>
<td>Artery dissection including aortic dissection may occur.</td>
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</tbody>
</table>

(Reference) Summary of Study Results Using National Database of Health Insurance Claims and Specific Health Checkup of Japan (NDB) (Evaluation of the risk of artery dissection due to systemic exposure to VEGF/VEGFR inhibitors):


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