Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

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

Pharmaceuticals and Medical Devices Agency

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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.

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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.

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

(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):
https://www.pmda.go.jp/files/000266522.pdf

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

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