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Translated by
Pharmaceuticals and Medical Devices Agency



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

Bevacizumab (genetical recombination)

Bevacizumab (genetical recombination) [Bevacizumab biosimilar 1]

Bevacizumab (genetical recombination) [Bevacizumab biosimilar 2]

June 16, 2020

Therapeutic category

Antineoplastics-miscellaneous

Non-proprietary name

Bevacizumab (genetical recombination), bevacizumab (genetical recombination) [bevacizumab biosimilar 1], bevacizumab (genetical recombination) [bevacizumab biosimilar 2]

Safety measure

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Adverse Reactions Clinically Significant Adverse Reactions (N/A)	Adverse Reactions Clinically Significant Adverse Reactions <u>Artery dissection:</u> <u>Artery dissection including aortic dissection may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.</u>

Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (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>

N/A: Not Applicable, because the section is not included in the current package insert.

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