Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Nivolumab (genetical recombination)

June 21, 2021

Therapeutic category

Other antitumor agents

Non-proprietary name

Nivolumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

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
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <Unresectable advanced or recurrent non-small cell lung cancer> Febrile neutropenia may occur when this drug is co-administered with carboplatin, paclitaxel, and bevacizumab (genetical recombination). The condition of patients should be carefully monitored through methods such as performing blood tests if necessary.
11. ADVERSE REACTIONS 11.1.5 Serious blood disorder Serious blood disorder such as immune thrombocytopenic purpura, haemolytic anaemia, or agranulocytosis may occur.	11. ADVERSE REACTIONS 11.1.5 Serious blood disorder Serious blood disorder such as immune thrombocytopenic purpura, haemolytic anaemia, agranulocytosis, or febrile neutropenia may occur. In addition, febrile neutropenia may occur when this drug is co-administered with carboplatin, paclitaxel, and bevacizumab (genetical recombination).

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

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp