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*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

## Nivolumab (genetical recombination)

May 9, 2019

### **Therapeutic category**

Antineoplastics-miscellaneous

### **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](mailto:safety.info@pmda.go.jp)

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
<p><b>Important Precautions</b></p> <p>Thyroid dysfunction may occur. <u>Thyroid</u> function tests (measurement of TSH, free T3, free T4, etc.) should be regularly performed prior to and during administration of this drug.</p> <p>Appropriate measures should be taken if <u>thyroid dysfunction</u> are observed <u>during administration of this drug.</u></p> <p><b>Adverse Reactions</b></p> <p><b>Clinically Significant Adverse Reactions</b></p> <p>(N/A)</p>	<p><b>Important Precautions</b></p> <p>Thyroid dysfunction, <u>pituitary impairment and adrenal disorder</u> may occur. <u>Endocrine</u> function test (measurement of TSH, free T3, free T4, <u>ACTH, blood cortisol, etc.</u>) should be performed prior to and periodically during administration of this drug. <u>In addition, imaging assessment, etc. should be considered to perform as well when required.</u> If any <u>abnormalities</u> are observed, appropriate measures should be taken.</p> <p><b>Adverse Reactions</b></p> <p><u>Clinically Significant Adverse Reactions</u></p> <p><u>Pituitary impairment:</u></p> <p><u>Pituitary impairment such as hypophysitis, hypopituitarism, and adrenocorticotrophic hormone deficiency may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.</u></p>

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

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