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.

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

Important Precautions
 	
  Thyroid dysfunction may occur. Thyroid function tests (measurement of TSH, free T3, free T4, etc.) should be regularly performed prior to and during administration of this drug. Appropriate measures should be taken if thyroid dysfunction are observed during administration of this drug.
	Important Precautions
	
	  Thyroid dysfunction, pituitary impairment and adrenal disorder may occur. Endocrine function test (measurement of TSH, free T3, free T4, ACTH, blood cortisol, etc.) should be performed prior to and periodically during administration of this drug. In addition, imaging assessment, etc. should be considered to perform as well when required. If any abnormalities are observed, appropriate measures should be taken.

Adverse Reactions
Clinically Significant Adverse Reactions
  (N/A)
	Adverse Reactions
	Clinically Significant Adverse Reactions
	  Pituitary impairment:
	  Pituitary impairment such as hypophysitis, hypopituitarism, and adrenocorticotropic hormone deficiency may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.

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