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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

## Secukinumab

### (genetical recombination)

January 21, 2020

#### **Therapeutic category**

Miscellaneous metabolism agents-Miscellaneous

#### **Non-proprietary name**

Secukinumab (genetical recombination)

#### **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>Erythroderma (dermatitis exfoliative):</u> <u>Erythroderma (dermatitis exfoliative) may occur. Patients should be carefully monitored and if any abnormalities are observed, appropriate measures such as discontinuing this drug 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>Erythroderma (dermatitis exfoliative)</u>

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

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