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Pharmaceuticals and Medical Devices Agency

Revision of Precautions

Ixekizumab (genetical recombination)

June 15, 2021

Therapeutic category

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Ixekizumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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>Interstitial pneumonia</u> <u>Cases of interstitial pneumonia have been reported. If cough, dyspnea, or pyrexia, etc. are observed, examinations such as chest X-ray, chest CT scan, and serum marker test should be performed immediately. If interstitial pneumonia is suspected, administration of this drug should be discontinued, and appropriate measures such as administration of corticosteroids should be taken.</u>

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