



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 Ustekinumab (genetical recombination)

October 18, 2016

Non-proprietary name

Ustekinumab (genetical recombination)

Safety measure

Precautions should be revised in the package insert.

In the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section, the following text should be added (underlined parts are revised):

Interstitial pneumonia:

Interstitial pneumonia may occur. If cough, dyspnea, pyrexia, and abnormal chest sound (crepitations), 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 adopted.

* Ustekinumab is designated as a drug requiring preparation of a Drug Guide for Patients.