



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

Infliximab

Aug 6, 2014

Non-proprietary Name

Infliximab (genetical recombination) (including follow-on biologics/biosimilars)

Safety measure

Precautions should be revised in the package inserts.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added:

Rhabdomyolysis:

Rhabdomyolysis may occur. Caution should be exercised for feeling of weakness, myalgia, increased creatine kinase (Creatine phosphokinase), and/or increased blood and urine myoglobin. If these symptoms are observed, administration of this drug should be discontinued and appropriate measures should be taken.

NOTE

- This drug is designated to prepare a Drug Guide for Patients.