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.