



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

Cyclophosphamide hydrate

March 24, 2015

Non-proprietary name

Cyclophosphamide hydrate

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reactions subsection of the Adverse reactions section, the following texts should be added (underlined parts are revised):

Rhabdomyolysis:

Rhabdomyolysis characterized by myalgia, feelings of weakness, increased creatine kinase (creatine phosphokinase), increased blood myoglobin, and increased urine myoglobin may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued and appropriate measures should be taken.