



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

Pramipexole hydrochloride hydrate

Aug 6, 2014

Non-proprietary Name

Pramipexole hydrochloride hydrate

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:

Hepatic dysfunction:

Hepatic dysfunction with elevations of aspartate aminotransferase (glutamate oxaloacetate transaminase), alanine aminotransferase (glutamate pyruvate transaminase), lactate dehydrogenase, γ-glutamyl transpeptidase, and/or total bilirubin 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.