Revision of PRECAUTIONS

Loratadine

July 8, 2014

Non-proprietary Name

Loratadine

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 (underlined parts are revised):

Convulsion:
Convulsion 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.