Revision of PRECAUTIONS

Tolvaptan

Aug 6, 2014

Non-proprietary Name
Tolvaptan

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:

Pancytopenia or thrombocytopenia:
Pancytopenia or thrombocytopenia may occur. Patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be taken.