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*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

## Tolvaptan

March 2018

### **Non-proprietary name**

Tolvaptan

### **Safety measure**

Precautions should be revised in the package insert.

The following language should be revised in the Clinically Significant Adverse Reactions subsection of the Adverse Reactions section (revised language is underlined):

Acute hepatic failure, hepatic impairment:

Hepatic impairment associated with increased levels of AST (GOT), ALT (GPT),  $\gamma$ -GTP, ALP, and bilirubin, etc. may occur and may lead to onset of acute hepatic failure. Patients should be observed carefully. If any abnormalities are observed, administration of this drug should be discontinued immediately and appropriate measures should be taken. Hepatic function should be closely monitored (through frequent blood tests, etc.) until the impairments are resolved.