



*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

## Entecavir Hydrate

February 16, 2016

### **Non-proprietary name**

Entecavir Hydrate

### **Safety measure**

Precautions should be revised in the package insert.

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

#### Hepatic function disorder:

AST and ALT may become elevated during treatment with this drug. If elevation in AST and ALT are observed, patients should be carefully monitored by conducting more frequent liver function tests, etc. If there are no signs of improvement in hepatic function based on test values, etc., appropriate measures such as discontinuation of administration should be adopted.