



# Summary of investigation results

## Adefovir pivoxil

July 7, 2015

### Non-proprietary name

Adefovir pivoxil

### Brand name (Marketing authorization holder)

Hepsera Tablets 10 (GlaxoSmithKline K.K.)

### Indications

Inhibition of hepatitis B virus replication in type B chronic liver disease, in which abnormality of liver function with replication of hepatitis B virus is confirmed

### Summary of revision

1. Alerts on fracture and measures in case of hypophosphatemia should be added to the Important precautions section.
2. 'Fracture' should be added to the Clinically significant adverse reactions section.

### Background of the revision and investigation results

Although there is the alert on osteomalacia caused by hypophosphatemia in the present precautions section, cases of fracture have been reported in patients treated with adefovir pivoxil in Japan. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.



*This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

**The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

A total of 43 cases\* of fracture have been reported. Of the 43 cases, no fatality has been reported.

\*Causal relationship of the fracture with adefovir pivoxil was not evaluated.