



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

Adefovir pivoxil

July 7, 2015

Non-proprietary name

Adefovir pivoxil

Safety measure

Precautions should be revised in the package insert.

Information on renal impairment in the Important precautions section should be revised as follows (underlined parts are revised):

Vigilance regarding the onset of renal impairment should be exercised by assessing renal function by measuring laboratory parameters such as serum creatinine during administration of this drug.

Osteomalacia and fracture caused by hypophosphatemia because of renal tubular disorder, including Fanconi syndrome, may occur. Prior to starting and during administration of this drug, levels of serum phosphorus, alkaline phosphatase, etc. should be measured, and the fluctuations should be periodically monitored. In addition, if hypophosphatemia is observed, appropriate measures such as phosphorus supplementation should be adopted. The administration of active vitamin D should be considered when supplementing phosphorus.

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

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Osteomalacia and fracture:

Osteomalacia and fracture associated with bone pain, arthralgia, and muscular weakness caused by hypophosphatemia because of renal tubular disorder, including Fanconi syndrome, may occur as a result of long-term administration. If this drug is administered for a long term, patients should be carefully monitored. If any abnormalities are observed, appropriate measures such as discontinuation of administration should be adopted.

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