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.

Summary of investigation results

Entecavir Hydrate

February 16, 2016

Non-proprietary name

Entecavir Hydrate

Brand name (Marketing authorization holder)

Baraclude Tablets 0.5 mg (Bristol-Myers K.K.)

Indications

Suppress replication of hepatitis B virus in chronic hepatitis B patients in whom hepatic function abnormalities associated with active viral replication of hepatitis B virus have been confirmed

Summary of revision

“Hepatic function disorder” should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of elevated AST and ALT have been reported during treatment with entecavir hydrate in Japan. It is difficult to distinguish this from the natural course of the primary disease since there are some cases in which elevated levels were resolving with continued treatment. However, there still are cases for which a causality to the drug could not be ruled out. 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.

Pharmaceuticals and Medical Devices Agency
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The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 11 cases associated with hepatic function disorder have been reported (including 4 cases for which a causal relationship to the product could not be ruled out). Of the 11 cases, 1 fatal case has been reported (a causal relationship between the product and the fatal outcome could not be established for this patient).

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