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Revision of Precautions

Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir

November 26, 2015

Non-proprietary name

Ombitasvir Hydrate/Paritaprevir Hydrate/Ritonavir

Safety measure

Precautions should be revised in the package insert.

In the Contraindications section regarding patients with severe hepatic function disorder (Child–Pugh Class C), the following text should be revised (underlined parts are revised):

Patients with moderate or severe hepatic function disorder (Child–Pugh Class B or C)

In the Important precautions section, the following text should be revised (underlined parts are revised):

Hepatic function disorder may occur. Periodic liver function tests should be performed during treatment. Hepatic function disorder is more likely to be observed within 4 weeks after the start of administration. Hepatic function should be assessed more frequently at the early stage after starting administration, as needed. Regardless of the increase in hepatic enzyme levels, blood bilirubin level may significantly increase, and hepatic failure may be observed along with ascites, hepatic encephalopathy etc. Patients should be carefully monitored. If any signs of liver failure are observed, appropriate measures should be adopted after the discontinuation of administration.

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

Hepatic function disorder, hepatic failure:
Hepatic function disorder associated with elevated ALT (GPT)* and/or bilirubin** levels etc. may occur. In addition, regardless of the hepatic enzyme increase, blood bilirubin levels may increase significantly, and the disorder may result in hepatic failure associated with ascites, hepatic encephalopathy etc. If there are any signs of an abnormality in hepatic function, the patient should be carefully monitored with more frequent laboratory tests. If worsening of symptoms is observed, appropriate measures should be adopted such as discontinuation of the administration. If the ALT (GPT) level persistently exceeds 10 times the upper limit of the standard value, or if any signs of hepatic failure are observed, administration of this drug should be discontinued and appropriate measures should be taken.
* More than 5 times the upper limit of the standard level, ** More than 3 times the upper limit of the standard level

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