MedWatch The FDA Safety Information and Adverse Event Reporting Program

Hepatitis C Treatments Viekira Pak and Technivie: Drug Safety Communication - Risk of Serious Liver Injury

[Posted 10/22/2015]

FDA 提出警告，治療 C 型肝炎藥品 Viekira Pak 與 Technivie 可能導致罹患潛在性晚期肝病患者出現嚴重肝損傷，部分不良反應案件造成患者進行肝臟移植或死亡。Viekira Pak 為內含 dasabuvir、ombitasvir、paritaprevir 與 ritonavir 的複方藥品；Technivie 則為含有 ombitasvir、paritaprevir、ritonavir 的複方藥品。FDA 已要求藥品製造商將嚴重肝損傷不良事件註記於藥品仿單中禁忌症、警語、上市後經驗等欄位。

建議

FDA 建議，醫護人員應密切監測患者服藥期間是否出現肝臟疾病惡化的徵兆，像是腹水、肝性腦病變、靜脈曲張出血、血液中直接膽紅素增加等。患者服藥時若出現疲勞、食慾不振、噁心嘔吐、皮膚眼睛發黃等症狀需馬上與醫護人員聯繫。FDA 也建議，患者不應在沒有告知醫療人員的情況下自行停藥，太早停用藥物可能引發 C 型肝炎的耐藥性。

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AUDIENCE: Patient, Infectious Disease, Pharmacy

ISSUE: FDA is warning that hepatitis C treatments Viekira Pak and Technivie can cause serious liver injury mostly in patients with underlying advanced liver disease. As a result, FDA is requiring the manufacturer to include information about serious liver injury adverse events to the Contraindications, Warnings and Precautions, Postmarketing Experience, and Hepatic Impairment sections of the Viekira Pak and Technivie drug labels.

FDA review of adverse events reported to the FDA Adverse Event Reporting System (FAERS) database and to the manufacturer of these medicines, AbbVie, identified cases of hepatic decompensation and liver failure in patients with underlying liver cirrhosis who were taking these medicines. Some of these events resulted in liver transplantation or death. These serious outcomes were reported mostly in patients taking Viekira Pak who had evidence of advanced cirrhosis even before starting treatment with it.

Since the approvals of Viekira Pak in December 2014 and Technivie in July 2015, at least 26 worldwide cases submitted to FAERS were considered to be possibly or probably related to Viekira Pak or Technivie. In most of the cases, liver injury occurred within 1 to 4 weeks of starting treatment. Some of the cases occurred in patients for whom these medicines were contraindicated or not recommended (see the Drug Safety Communication Data Summary section). FAERS includes only reports submitted to FDA, so there

are likely additional cases about which FDA is unaware.

BACKGROUND: Viekira Pak and Technivie are used to treat chronic hepatitis C. Viekira Pak is a fixed-dose combination of dasabuvir, ombitasvir, paritaprevir, and ritonavir used with or without ribavirin, another hepatitis C medicine. Technivie is a fixed-dose combination of ombitasvir, paritaprevir, and ritonavir, used in combination with ribavirin.

RECOMMENDATION: Health care professionals should closely monitor for signs and symptoms of worsening liver disease, such as ascites, hepatic encephalopathy, variceal hemorrhage, and/or increases in direct bilirubin in the blood.

Patients taking these medicines should contact their health care professional immediately if they develop fatigue, weakness, loss of appetite, nausea and vomiting, yellow eyes or skin, or light-colored stools, as these may be signs of liver injury. Patients should not stop taking these medicines without first talking to their health care professionals. Stopping treatment early could result in drug resistance to other hepatitis C medicines.