AMERICAN HEALTH CARE
DRUG PRODUCTS & SAFETY NEWS

FDA Approves Zepatier

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The U.S. Food and Drug Administration (FDA) approved Zepatier (elbasvir and grazoprevir) with or without ribavirin for the treatment of chronic hepatitis C virus (HCV) genotypes 1 and 4 infections in adult patients.

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with HCV have no symptoms of the disease until liver damage becomes apparent, which may take years. Some people with chronic HCV infection develop cirrhosis over many years, which can lead to complications such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections or liver cancer. According to the Centers for Disease Control and Prevention, approximately 3 million Americans are infected with HCV, of which genotype 1 is the most common and genotype 4 is one of the least common.

Zepatier was granted breakthrough therapy designation for the treatment of chronic HCV genotype 1 infection in patients with end stage renal disease on hemodialysis and for the treatment of chronic HCV genotype 4 infection.

The most common side effects of Zepatier without ribavirin were fatigue, headache, and nausea. The most common side effects of Zepatier with ribavirin were anemia and headache.

Zepatier is marketed by Merck & Co. Inc. based in Whitehouse Station, New Jersey.

Healthcare professionals and patients are encouraged to report any adverse events or side effects related to the use of this product and/or quality problems to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- ✓Complete and submit the report online: www.fda.gov/MedWatch/report.htm
- ✓Complete and return a form by mail (address on the pre-addressed form) or fax (1-800-FDA-0178).

[Call 1-800-332-1088 to request a reporting form or download a form at http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm.]

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