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URGENT NOTICE

TYPE: Drug Safety Communication

Hepatitis C treatments containing Sofosbuvir in combination with another direct acting antiviral - serious slowing of heart rate when used with antiarrhythmic drug Amiodarone

Drug Name: **Harvoni-Amiodirone Drug Interaction**

Audience: Cardiology, Infectious Disease, Gastroenterology, Pharmacy

Date: **03/24/2015**

ISSUE

FDA is warning that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together with either the hepatitis C drug Harvoni (ledipasvir/sofosbuvir) or with Sovaldi (sofosbuvir) taken in combination with another direct acting antiviral for the treatment of hepatitis C infection. FDA is adding information about serious slowing of the heart rate, known as symptomatic bradycardia, to the Harvoni and Sovaldi labels. FDA is recommending that health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct acting antiviral, such as the investigational drug daclatasvir or Olysio (simeprevir), with amiodarone.

FDA review of submitted postmarketing adverse event reports found that patients can develop a serious and life-threatening symptomatic bradycardia when either Harvoni or Sovaldi combined with another direct-acting antiviral is taken together with amiodarone. The reports included the death of one patient due to cardiac arrest and three patients requiring placement of a pacemaker to regulate their heart rhythms. The other patients recovered after discontinuing either the hepatitis C drugs or amiodarone, or both. The cause of these events could not be determined. FDA will continue to monitor Harvoni and Sovaldi for risks of serious symptomatic bradycardia and further investigate the reason why the use of amiodarone with these hepatitis C drugs led to the heart-related events.

BACKGROUND

For a Data Summary and additional recommendations for health professionals and patients, see the FDA Drug Safety Communication or call (888) 463-6332 or visit FDA.gov.

RECOMMENDATION

Health care professionals should not prescribe either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone. However, in cases where alternative treatment options are unavailable, FDA recommends heart monitoring in an inpatient hospital setting for the first 48 hours. Subsequently, monitoring in a doctor's office or self-monitoring of the heart rate should be done every day through at least the first 2 weeks of treatment.

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Due to the long half-life of amiodarone, patients discontinuing amiodarone just prior to starting Harvoni, or Sovaldi in combination with another direct-acting antiviral, should also undergo similar cardiac monitoring as outlined above.

Patients taking either Harvoni or Sovaldi combined with another direct-acting antiviral drug with amiodarone should seek medical attention right away if they experience signs or symptoms of symptomatic bradycardia such as:

- Near-fainting or fainting
- Dizziness or light-headedness
- Malaise
- Weakness
- Excessive tiredness
- Shortness of breath
- Chest pains
- Confusion or memory problems