

FDA approved changes to the Olysio (simeprevir) package insert to include two new Warnings and Precautions;

Summary of new WARNINGS AND PRECAUTIONS

Serious Symptomatic Bradycardia When Co-administered with Sofosbuvir and Amiodarone

Postmarketing cases of symptomatic bradycardia and cases requiring pacemaker intervention have been reported when amiodarone is co administered with sofosbuvir in combination with another HCV direct acting antiviral, including OLYSIO. A fatal cardiac arrest was reported in a patient receiving a sofosbuvir-containing regimen (ledipasvir/sofosbuvir). Bradycardia has generally occurred within hours to days, but cases have been observed up to 2 weeks after initiating HCV treatment. Patients also taking beta blockers, or those with underlying cardiac comorbidities and/or advanced liver disease may be at increased risk for symptomatic bradycardia with co administration of amiodarone. Bradycardia generally resolved after discontinuation of HCV treatment. The mechanism for this bradycardia effect is unknown. Co administration of amiodarone with OLYSIO in combination with sofosbuvir is not recommended. For patients taking amiodarone who have no other alternative treatment options, and who will be co administered OLYSIO and sofosbuvir:

Counsel patients about the risk of serious symptomatic bradycardia

Cardiac monitoring in an in-patient setting for the first 48 hours of co administration is recommended, after which outpatient or self-monitoring of the heart rate should occur on a daily basis through at least the first 2 weeks of treatment.

Patients who are taking sofosbuvir in combination with OLYSIO who need to start amiodarone therapy due to no other alternative treatment options should undergo similar cardiac monitoring as outlined above.

Due to amiodarone's long elimination half-life, patients discontinuing amiodarone just prior to starting sofosbuvir in combination with OLYSIO should also undergo similar cardiac monitoring as outlined above.

Patients who develop signs or symptoms of bradycardia should seek medical evaluation immediately. Symptoms may include near-fainting or fainting, dizziness or lightheadedness, malaise, weakness, excessive tiredness, shortness of breath, chest pain, confusion or memory problems [see Adverse Reactions (6.2) and Drug Interactions

Hepatic Decompensation and Hepatic Failure

Hepatic decompensation and hepatic failure, including fatal cases, have been reported postmarketing in patients treated with OLYSIO in combination with peginterferon alfa and ribavirin or in combination with sofosbuvir. Most cases were reported in patients with advanced and/or decompensated cirrhosis who are at increased risk for hepatic decompensation or hepatic failure. Because these events have been reported voluntarily during clinical practice, estimates of frequency cannot be made and a causal relationship between treatment with OLYSIO and these events has not been established. OLYSIO is not recommended for patients with moderate or severe hepatic impairment.

<http://hepatitisnewdrugs.blogspot.com/2015/04/fda-approved-changes-to-olysio.html>