U.S. FDA Updates on Hepatitis C Treatment Drugs

December 13, 2017 By Connie M. Welch

The Sovaldi (sofosbuvir), Harvoni (ledipasvir and sofosbuvir), Epclusa (sofosbuvir and velpatasvir) and Vosevi (sofosbuvir, velpatasvir, and voxilaprevir) labels were updated to include information pertaining to changes in International Normalized Ratio (INR) values in patients receiving warfarin.

Section 7: DRUG INTERACTIONS was updated to state fluctuations in INR values may occur in patients receiving warfarin concomitant with HCV treatment. Frequent monitoring of INR values is recommended during treatment and post-treatment follow-up.

The Harvoni, Epclusa, and Vosevi labels were updated to include drug interaction information when these drugs are used with atorvastatin because coadministration of these drugs with atorvastatin may be associated with increased risk of myopathy (resulting in muscle weakness) including rhabdomyolysis (a condition in which damaged skeletal muscle breaks down rapidly), and to monitor closely for HMG-CoA reductase inhibitor-associated adverse reactions, such as myopathy and rhabdomyolysis.

Section 12: CLINICAL PHARMACOLOGY was updated to state when a single 40 mg dose of atorvastatin was given with Epclusa, atorvastatin AUC and Cmax increased 54% and 68%, respectively.

FDA updates on the following Hepatitis C treatment drugs continue with;

VIEKIRA PAK™ (ombitasvir, paritaprevir, and ritonavir tablets, 12.5 mg/75 mg/50 mg; dasabuvir tablets, 250 mg), VIEKIRA XR (dasabuvir, ombitasvir, paritaprevir, and ritonavir), and TECHNIVIE (ombitasvir, paritaprevir, and ritonavir) labels were updated to include information pertaining to changes in International Normalized Ratio (INR) values in patients receiving warfarin.

The following sections were updated:

Section 6: Adverse Reactions the following statement was deleted – There were no serious events or severe cutaneous reactions, such as Stevens Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), erythema multiforme (EM) or drug rash with eosinophilia and systemic symptoms (DRESS).

Section 6.2 Post-Marketing Experience the following information was added to Skin and Subcutaneous Tissue Disorders: Erythema multiforme (EM).

Section 7: Drug Interactions was updated to state fluctuations in INR values may occur in patients receiving warfarin concomitant with HCV treatment. If coadministered with warfarin, close monitoring of INR values is recommended during treatment and post-treatment follow-up.

For Hepatitis C treatment drugs OLYSIO (simeprevir), DAKLINZA (daclatasvir) and ZEPATIER (grazoprevir/elbasvir) labels were updated to include information pertaining to changes in International Normalized Ratio (INR) values in patients receiving warfarin.

Section 7: DRUG INTERACTIONS was updated to state fluctuations in INR values may occur in patients receiving warfarin concomitant with HCV treatment. Frequent monitoring of INR values is recommended during treatment and post-treatment follow-up.

The updated label will soon be available at drugs@fda or DailyMed

If you are taking warfarin or any blood thinners, talk to your doctor and make sure to receive testing throughout your Hepatitis treatment and post treatment recovery to insure your INR values are where they need to be. If you are in treatment for Hepatitis C report all side effects you experience to your physician for follow up.

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