Prestalia® (perindopril/amlodipine) – New and Updated Warnings

- On November 23, 2016, the FDA approved new and updated safety information to the *Warnings and Precautions* section of the Prestalia (perindopril/amlodipine) drug label, pertaining to hepatic failure and the risk of acute renal failure in patients taking nonsteroidal anti-inflammatory drugs (NSAIDs) or angiotensin receptor blockers (ARBs).

- Prestalia is indicated for the treatment of hypertension, to lower blood pressure.

    - Prestalia may be used in patients not adequately controlled with monotherapy, and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals.

- Rarely, ACE inhibitors have been associated with a syndrome that starts with cholestatic jaundice and progresses to fulminant hepatic necrosis and sometimes death. The mechanism of this syndrome is not understood. Patients receiving ACE inhibitors who develop jaundice or marked elevations of hepatic enzymes should discontinue the ACE inhibitor and receive appropriate medical follow-up.

- In addition, the *Impaired Renal Function* section was updated to include the risk of developing acute renal failure with Prestalia in patients who are on NSAIDs or ARBs.

    - Renal function should be monitored periodically in patients receiving Prestalia.
    - Drugs that affect the renin-angiotensin system can cause reductions in renal function, including acute renal failure.
    - Patients whose renal function may depend in part on the activity of the renin-angiotensin system (eg, patients with renal artery stenosis, severe heart failure, post-myocardial infarction or volume depletion) or who are on NSAIDs or ARBs may be at particular risk of developing acute renal failure on Prestalia.
    - Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in renal function on Prestalia.

- Other updates were made to the *Dosage Adjustment in Renal Impairment* subsection, *Clinical Pharmacology* section, and *Use in Specific Populations* section, including the deletion of subsection 8.7 (*Hepatic Impairment*) and subsection 8.8 (*Heart Failure*).

- Prestalia carries a boxed warning regarding fetal toxicity.