Amitiza® (lubiprostone) – New Warning

- The FDA approved a new update to the *Warnings and Precautions* section of the Amitiza (lubiprostone) drug label regarding syncope and hypotension.

- Amitiza is indicated for the treatment of chronic idiopathic constipation in adults, treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain, and treatment of irritable bowel syndrome with constipation (IBS-C) in women ≥ 18 years old.

    - Effectiveness of Amitiza in the treatment of OIC in patients taking diphenylheptane opioids (eg, methadone) has not been established.

- Syncope and hypotension have been reported with Amitiza in the postmarketing setting and a few of these adverse reactions resulted in hospitalization. Most cases occurred in patients taking 24 mcg twice daily and some occurred within an hour after taking the first dose or subsequent doses of Amitiza.

    - Some patients had concomitant diarrhea or vomiting prior to developing the adverse reaction.
    - Syncope and hypotension generally resolved following Amitiza discontinuation or prior to next dose, but recurrence has been reported with subsequent doses.
    - Several cases reported concomitant use of medications known to lower blood pressure, which may increase the risk for the development of syncope or hypotension.

- Patients should be aware of the risk of syncope and hypotension during treatment and that other adverse reactions may increase this risk, such as diarrhea or vomiting.