Proton Pump Inhibitors – New Warning

- On October 24, 2016, the FDA approved new updates to the *Warnings and Precautions* section of the drug labels for the proton pump inhibitors (PPIs), pertaining to serious cutaneous lupus erythematosus (CLE) and systemic lupus erythematosus (SLE).

- FDA-approved PPIs include rabeprazole (Aciphex®, Aciphex® Sprinkles™), dexlansoprazole (Dexilant™, Dexilant™ SoluTab), esomeprazole (Nexium®, Nexium® I.V.), lansoprazole (Prevacid®, Prevacid® SoluTab), omeprazole (Prilosec®), pantoprazole (Protonix®, Protonix® I.V.), esomeprazole/naproxen (Vimovo®), and omeprazole/sodium bicarbonate (Zegerid®).

    - All PPIs are available generically except for Dexilant and Vimovo.
    - Nexium, Prevacid, and Prilosec are also available as over-the-counter (OTC) medications.

- PPIs are commonly used to treat certain gastrointestinal disorders such as duodenal ulcer, gastric ulcer, and gastroesophageal reflux disease (GERD).

    - Vimovo, which contains the PPI, esomeprazole, is indicated for relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing nonsteroidal anti-inflammatory drug (NSAID)-associated gastric ulcers.

- CLE and SLE have been reported in patients taking PPIs. These events have occurred as both new onset and an exacerbation of existing autoimmune disease. The majority of PPI-induced lupus erythematosus cases were CLE.

    - The most common form of CLE reported in patients treated with PPIs was subacute CLE and occurred within weeks to years after continuous drug therapy in patients ranging from infants to the elderly. Generally, histological findings were observed without organ involvement.
    - SLE is less commonly reported than CLE in patients receiving PPIs. PPI associated SLE is usually milder than non-drug induced SLE.
    - Onset of SLE typically occurred within days to years after initiating treatment primarily in patients ranging from young adults to the elderly. The majority of patients presented with rash; however, arthralgia and cytopenia were also reported.
    - Avoid administration of PPIs for longer than medically indicated.
    - If signs or symptoms consistent with CLE or SLE are noted in patients receiving PPIs, discontinue the drug and refer the patient to the appropriate specialist for evaluation.
    - Most patients improve with discontinuation of the PPI alone in 4 - 12 weeks.
    - Serological testing (eg, ANA) may be positive and elevated serological test results may take longer to resolve than clinical manifestations.