Gloperba® (colchicine) – New drug approval

- On January 31, 2019, the FDA approved Romeg Therapeutics' Gloperba (colchicine) oral solution for prophylaxis of gout flares in adults.
    - The safety and efficacy of Gloperba for acute treatment of gout flares during prophylaxis has not been studied. Gloperba is not an analgesic medication and should not be used to treat pain from other causes.
- The evidence for the efficacy of colchicine in patients with chronic gout is derived from the published literature. Two randomized clinical trials assessed the efficacy of colchicine 0.6 mg twice a day for the prophylaxis of gout flares in patients with gout initiating treatment with urate-lowering therapy. In both trials, treatment with colchicine decreased the frequency of gout flares.
- Colchicine is currently available as brand and generic capsule (Mitigare®) and tablet formulations (Colcrys®).
- Gloperba is contraindicated in patients with renal or hepatic impairment. Gloperba should not be given to these patients in conjunction with drugs that inhibit CYP3A4 and P-gp.
- Warnings and precautions of Gloperba include fatal overdose, blood dyscrasias, drug interactions, and neuromuscular toxicity.
- The most commonly reported adverse reactions with Gloperba use were gastrointestinal symptoms, including diarrhea, nausea, vomiting, and abdominal pain.
- The recommended dose for Gloperba is 0.6 mg (5 mL) orally once or twice daily. The maximum dose is 1.2 mg/day.
- Romeg Therapeutics plans to launch Gloperba by mid July 2019. Gloperba will be available as a 0.6 mg/5 mL oral solution.