Dartisla ODT™ (glycopyrrolate) – New drug approval

- On December 17, 2021, Edenbridge Pharmaceuticals announced the FDA approval of Dartisla ODT (glycopyrrolate) orally disintegrating tablets, in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer.
    - Dartisla ODT is not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established.
- Glycopyrrolate is currently available generically as an oral tablet formulation for adjunctive therapy in the treatment of peptic ulcer.
- Dartisla ODT is contraindicated in patients at risk for anticholinergic toxicity due to an underlying medical condition and patients with a hypersensitivity to glycopyrrolate or any of the inactive ingredients in Dartisla ODT.
- Warnings and precautions for Dartisla ODT include precipitation of acute glaucoma; partial or complete mechanical intestinal obstruction; gastrointestinal adverse reactions due to decreased gastrointestinal motility; cognitive and visual adverse reactions; heat prostration at high environmental temperatures; other conditions exacerbated by anticholinergic adverse reactions; and increased risk of anticholinergic adverse reactions in geriatric patients.
- The most common adverse reactions with Dartisla ODT use are blurred vision, drowsiness, decreased sweating, flushing, vomiting, constipation, dry mouth, tachycardia, and urinary retention.
- The recommended dosage of Dartisla ODT is 1.7 mg given two or three times daily administered on top of the tongue. The tablet should be allowed to disintegrate and then swallowed without water. The maximum recommended daily dosage is 6.8 mg.
    - Patients receiving the 2 mg dosage strength of another oral tablet dosage formulation of glycopyrrolate may be switched to the 1.7 mg dosage strength of Dartisla ODT.
    - Dartisla ODT is not recommended for patients in whom a lower dosage strength of another oral glycopyrrolate product (eg, tablet strength of 1 mg) is appropriate for initial or maintenance treatment because the dosage strength of Dartisla ODT may exceed the recommended initial and maintenance dosage of other oral glycopyrrolate products.
- Edenbridge Pharmaceuticals plans to launch Dartisla ODT in early 2022. Dartisla ODT will be available as a 1.7 mg orally disintegrating tablet.