New drug information

- **Thiola EC® (tiopronin delayed-release) 100 mg, 300 mg tablets**: Mission Pharmacal/Retrophin’s Thiola EC has been granted approval from the U.S. Food and Drug Administration (FDA) in combination with high fluid intake, alkali, and diet modification, for the prevention of cystine stone formation in adults and pediatric patients 20 kg and greater with severe homozygous cystinuria. Thiola immediate-release is currently available as 100 mg tablets. Immediate-release tablets should be administered at least one hour before or two hours after meals with an average dosage of 1000 mg (10 tablets/day) in 3 divided doses. Thiola EC is taken with or without food with an average dosage of 1000 mg (4 tablets/day) in 3 divided doses. Retrophin plans to launch Thiola EC in July, but has not announced pricing.¹

- **Katerzia™ (amlodipine benzoate)**: The FDA approved Silvergate Pharm’s Katerzia for the treatment of hypertension in adults and children 6 years and older, to lower blood pressure; and coronary artery disease (chronic stable angina, vasospastic angina, angiographically documented coronary artery disease in patients without heart failure or an ejection fraction < 40%). Katerzia is the first amlodipine formulation in a ready-to-use oral suspension. Launch date is expected in September with pricing to follow.²

- **Recarbrio™ (imipenem, cilastatin and relebactam)**: Merck’s Recarbrio intravenous injection has been granted approval for the treatment of adults with complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI). Recarbrio is a three-drug combination injection containing imipenem-cilastatin, a previously FDA-approved antibiotic, and relebactam, a new beta-lactamase inhibitor. Recarbrio should be reserved for situations when there are limited or no alternative antibacterial drugs for treating a patient's infection. Recarbrio will launch by the end of 2019; pricing has not been released.³

- **Drizalma Sprinkle™ (duloxetine delayed-release capsules)**: Sun Pharmaceuticals’ Drizalma Sprinkle has been approved by the FDA for treatment of major depressive disorder in adults; generalized anxiety disorder in adults and pediatric patients ages 7 to 17 years old; diabetic peripheral neuropathic pain in adults; and chronic musculoskeletal pain in adults. Drizalma Sprinkle may be swallowed whole (do not crush or chew capsule), opened and sprinkled over applesauce; or administered via nasogastric tube. Lilly’s Cymbalta (duloxetine delayed-release capsules) is also approved for similar indications; as well as fibromyalgia, but should not be crushed or chewed and the capsule should not be opened. Drizalma Sprinkle launch and pricing have not been released.⁴
Generic drug information


- **Uloric® (febuxostat):** Multiple manufacturers have launched their generic versions of Takeda’s Uloric for the treatment of gout. Uloric generated $578 million in U.S. annual sales in 2018.

- **Hemabate® (carboprost injection):** Dr. Reddy’s have launched the first generic version of Pfizer’s Hemabate for the termination of pregnancy and for the treatment of postpartum hemorrhage. No other generic manufacturers appear to be pursuing generic versions of Hemabate. Hemabate generated $50 million in U.S. annual sales in 2018.

- **Lyrica® (pregabalin):** Multiple manufacturers have launched their generic versions of Pfizer’s Lyrica for neurological pain, seizures, and fibromyalgia. Lyrica generated $5.465 billion in U.S. annual sales in 2018.

References


4. [https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212516s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212516s000lbl.pdf)

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