New drug information

- **Carnexiv™ (carbamazepine):** The U.S. Food and Drug Administration (FDA) approved an intravenous formulation of carbamazepine for use as replacement therapy in adults who are on a stable maintenance dose of carbamazepine to control seizures when oral administration is temporarily not feasible.

New generics

- **Cordran® (flurandrenolide) lotion:** Perrigo Pharmaceuticals has launched a generic version of Aqua Pharmaceuticals Cordran lotion for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

- **Vagifem® (Yuvafem® — estradiol vaginal tab):** Amneal Pharmaceuticals has launched the first generic version of Novo Nordisk’s Vagifem for the treatment of atrophic vaginitis due to menopause. Amneal will have 180 days of marketing exclusivity. According to IMS Health, Vagifem had approximately $423 million in annual U.S. sales.

October news:

- “Newron Pharmaceuticals re-submitted a new drug application (NDA) to the FDA for Parkinson’s disease (PD) candidate Xadago (safinamide). In March, the FDA issued a complete response letter for Xadago as an add-on therapy for early and mid-to-late stage PD in patients who are inadequately managed on their current treatments.”

- “The FDA has accepted for priority review an NDA for valbenazine (Ingrezza™, Neurocrine Biosciences) for the treatment of patients with tardive dyskinesia (TD). The NDA has been given a target action date of April 11, 2017.”

- “The FDA published 67 generic drug-specific recommendations (34 new and 33 revised) describing the agency’s expectations for developing generics that are therapeutically equivalent to reference-listed drugs (RLDs). The guidance is intended to help the generic pharmaceutical industry identify the most appropriate ways to generate evidence needed to support abbreviated new drug application (ANDA) approval.”

References


While the information in this newsletter is from sources we believe to be reliable, we do not warrant that the information in this document is free from error. Use it only as a guide. Statements regarding drugs or manufacturers are not intended as promotion; those statements should not be used to make assumptions about formulary status. All brand names are property of their respective owners.

2992-01 © Prime Therapeutics LLC 10/16