

Carnexiv[™] (carbamazepine) – New Orphan Drug Approval

- On October 7, 2016, <u>Lundbeck announced</u> the FDA approval of <u>Carnexiv (carbamazepine)</u> injection as replacement therapy for oral carbamazepine formulations, when oral administration is temporarily not feasible, in adults with the following seizure types:
 - Partial seizures with complex symptomatology
 - Generalized tonic-clonic seizures
 - Mixed seizure patterns which include the above, or other partial or generalized seizures
- Carnexiv is not indicated for the treatment of absence seizures (including atypical absence).
 Carbamazepine has been associated with increased frequency of generalized convulsions in these patients.
- The efficacy of Carnexiv is based upon bioavailability studies comparing oral carbamazepine to Carnexiv.
 The pharmacokinetics of the principal metabolite of carbamazepine were similar following both intravenous and oral dosing.
- Similar to the oral formulations of carbamazepine, Carnexiv carries a boxed warning for serious dermatologic reactions and aplastic anemia and agranulocytosis.
- Other warnings and precautions of Carnexiv include impairment of renal function, drug reaction with
 eosinophilia and systemic symptoms (DRESS)/multiorgan hypersensitivity, suicidal behavior and ideation,
 embryofetal toxicity, abrupt discontinuation and seizure risk, hyponatremia, potential impairment of
 neurologic function, hepatic toxicity, increased intraocular pressure, and hepatic porphyria.
- The most common adverse reactions (≥ 2%) with Carnexiv use were dizziness, somnolence, blurred vision, diplopia, headache, infusion-related reaction, infusion site pain, and anemia.
- The total daily dose of Carnexiv is 70% of the total daily oral carbamazepine dose from which patients are being switched. The total daily dose of Carnexiv should be equally divided into four 30-minute intravenous infusions separated by 6 hours.
 - Patients should be switched back to oral carbamazepine administration at their previous total daily oral dose and frequency of administration as soon as clinically appropriate.
 - The use of Carnexiv for more than 7 days has not been studied and is not recommended.
- Lundbeck plans to launch Carnexiv in early 2017 as 200 mg/20mL (10 mg/mL) single dose vials.



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