

Quzyttir[™] (cetirizine) – New drug approval

- On October 4, 2019, the [FDA approved](#) TerSera Therapeutics' [Quzyttir \(cetirizine\)](#) injection, for the treatment of acute urticaria in adults and children 6 months of age and older.
 - Quzyttir is not recommended in pediatric patients less than 6 years of age with impaired renal or hepatic function.
- Quzyttir is the first FDA approved intravenous (IV) formulation of cetirizine. Oral formulations of cetirizine are available generically as [prescription](#) as well as well over-the-counter (OTC) (eg, [Zyrtec](#)[®]).
 - Prescription oral cetirizine is approved for perennial allergic rhinitis and chronic urticaria.
 - Zyrtec and other OTC products are approved for use to temporarily relieve symptoms due to hay fever or other upper respiratory allergies: runny nose, sneezing, itchy and watery eyes, and itching of the nose or throat.
- The efficacy of Quzyttir was established in a randomized, active-controlled, double-blind, single-dose study in 262 adult patients with acute urticaria. Patients were treated with Quzyttir or [diphenhydramine](#) injection. The primary efficacy endpoint was the change from baseline in patient-rated pruritus score assessed 2 hours post treatment. The study was non-inferiority design with the pre-specified non-inferiority margin of 0.50 for the difference between treatment groups.
 - The effectiveness of Quzyttir was demonstrated to be non-inferior to the effectiveness of diphenhydramine. The mean change from baseline in patient-rated pruritus score was -1.61 and -1.50 for Quzyttir and diphenhydramine, respectively (adjusted difference: 0.06; 95% CI: -0.28, 0.40).
- The efficacy of Quzyttir for the treatment of acute urticaria down to 6 months of age is based on extrapolation of the efficacy of Quzyttir in adults with acute urticaria and supported by pharmacokinetic data with oral cetirizine hydrochloride in patients 6 months to 17 years of age.
- A warnings and precaution for Quzyttir is somnolence/sedation.
- The most common adverse reactions (< 1%) with Quzyttir use were dysgeusia, headache, paresthesia, presyncope, dyspepsia, feeling hot, and hyperhidrosis.
- The recommended dosage regimen for Quzyttir is once every 24 hours as needed. Quzyttir should be administered as an IV push over a period of 1 to 2 minutes. The recommended dosage is based on age:
 - Adults and adolescents 12 years of age and older: 10 mg
 - Children 6 to 11 years of age: 5 mg or 10 mg depending on symptom severity
 - Children 6 months to 5 years of age: 2.5 mg.
- TerSera Therapeutics' launch plans for Quzyttir are pending. Quzyttir will be available as a 10 mg/mL injection.