

Generic Name:

Imipenem, cilastatin, and relebactam

Trade Name:

Recarbrio

Company:

Merck

Notes:

FDA has [approved](#) imipenem, cilastatin, and relebactam, an antibacterial drug product to treat adults with complicated urinary tract infections (cUTI) and complicated intra-abdominal infections (cIAI).

The three-drug combination injection contains imipenem-cilastatin, a previously FDA-approved antibiotic, and relebactam, a new beta-lactamase inhibitor.

The determination of efficacy was supported in part by the findings of the efficacy and safety of imipenem-cilastatin for treatment of cUTI and cIAI. The contribution of relebactam was assessed on the basis of data from in vitro studies and animal models of infection. Safety was studied in two trials, one each for cUTI and cIAI. The cUTI trial included 298 adult patients, with 99 treated with the proposed dose of the combination drug. The cIAI trial included 347 patients with 117 treated with the proposed dose.

The most common adverse reactions observed in patients included nausea, diarrhea, headache, fever and increased liver enzymes.

The agent should not be used in patients taking ganciclovir unless the benefits outweigh the risks, as generalized seizures have been reported. Patients should also avoid using the drug when taking valproic acid or divalproex sodium, drugs used to manage seizures, as a reduction in valproic acid level may lead to seizures.

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