

FDA OKs urinary infection injectable drug

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The U.S. Food and Drug Administration announced approval Thursday of doripenem (Doribax) injections for the treatment of complex urinary tract infections.

The 500 mg intravenous infusion, also used to treat intra-abdominal infections, have been shown to be active against several strains of bacteria, the FDA said.

"This is a significant new drug in the treatment of hospitalized patients with serious bacterial infections," said Dr. Janet Woodcock, the FDA's deputy commissioner for scientific and medical programs.

Officials said doripenem, in several multi-center, multinational studies, was shown to have a cure rate comparable to the currently prescribed medications levofloxacin, used for complicated urinary tract infections, and meropenem, indicated for complicated intra-abdominal infections.

However, the FDA said the safety and effectiveness of doripenem injection in pediatric patients and pregnant women has not been established.

Doripenem injection is manufactured under the brand name Doribax by Johnson and Johnson Pharmaceutical Research and Development LLC of Raritan, N.J.

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