FDA approves generic Emflaza oral suspension for Duchenne muscular dystrophy

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The U.S. Food and Drug Administration has approved the first generic version of Emflaza (deflazacort) oral suspension for Duchenne muscular dystrophy (DMD). Approval of the generic version of Emflaza oral

suspension was granted to Cranbury Pharmaceuticals (Tris Pharma).

Deflazacort oral suspension is a corticosteroid indicated to treat DMD in patients 5 years of age and older but is contraindicated in patients with known hypersensitivity to deflazacort. The most common adverse reactions reported in patients were Cushingoid appearance, weight increase, increase in appetite, upper respiratory tract infection, cough, pollakiuria, hirsutism, central obesity, and nasopharyngitis.

"Duchenne muscular dystrophy is a devastating rare disease, and with limited treatment options available there is a critical need for the greater accessibility that a generic therapy can bring," Ketan Mehta, the founder and CEO of Tris Pharma, said in a statement.

"This FDA approval is a significant milestone for the patients, caregivers, and physicians who may depend on this medication to treat DMD."

More information: More Information

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