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USFDA approves Lupin's Dimethyl Fumarate Delayed-Release Capsules

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Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg, are indicated for the treatment of patients with relapsing forms of multiple sclerosis



Pharma major Lupin Limited (Lupin) announced that it has received approval for its Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg, from the United States Food and Drug Administration (US FDA), to market a generic equivalent of Tecfidera® Delayed-Release Capsules, 120 mg and 240 mg, of Biogen, Inc. The product is expected to be launched shortly.

Dimethyl Fumarate Delayed-Release Capsules, 120 mg and 240 mg, are indicated for the treatment of patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Dimethyl Fumarate Delayed-Release Capsules (RLD: Tecfidera®) had an annual sales of approximately \$3788 million in the US (IQVIA MAT June 2020).