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FDA approves Lupin’s Penicillamine Tablets USP

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The product would be manufactured at Lupin’s Nagpur facility and is expected to be launched shortly

Pharma major Lupin Limited announced that it has received approval for its Penicillamine Tablets USP, 250 mg, from the United States Food and Drug Administration (US FDA), to market a generic equivalent of Depen® Tablets, 250 mg, of Mylan Specialty, LP. The product would be manufactured at Lupin’s Nagpur facility and is expected to be launched shortly.

Penicillamine Tablets USP, 250 mg, are indicated in the treatment of Wilson’s disease, Cystinuria, and in patients with severe, active rheumatoid arthritis who have failed to respond to an adequate trial of conventional therapy.

Penicillamine Tablets USP (RLD: Depen®) had an annual sales of approximately $4 million in the US (IQVIA MAT September 2020).