

Lupin gets FDA nod for Extended Phenytoin Sodium capsules

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It is a generic equivalent of Dilantin® 100 mg of Parke-Davis



Pharma major Lupin Limited (Lupin) announced that it has received approval for its extended Phenytoin Sodium Capsules USP, 100 mg, from the United States Food and Drug

Administration (U.S.FDA), to market a generic equivalent of Dilantin® 100 mg, of Parke-Davis, division of Pfizer Inc.

Lupin's Extended Phenytoin Sodium Capsules USP, 100 mg, are indicated for:

- Treatment of tonic-clonic (grand mal) and psychomotor (temporal lobe) seizures
- Prevention and treatment of seizures occurring during or following neurosurgery

Extended Phenytoin Sodium Capsules USP, 100 mg (RLD: Dilantin®) had annual sales of approximately USD 105 million in the U.S. (IQVIA MAT June 2019).