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Search Orphan Drug Designations and Approvals

Generic Name:	phenobarbital sodium
Trade Name:	Sezaby
Date Designated:	10/02/2019
Orphan Designation:	Treatment of neonatal seizures
Orphan Designation Status:	Designated/Approved
Sponsor:	Sun Pharmaceutical Industries, Inc. 2 Independence Way Princeton, New Jersey 08540 United States
<i>The sponsor address listed is the last reported by the sponsor to OOPD.</i>	
Marketing approved:	
Generic Name:	phenobarbital sodium
Trade Name:	Sezaby
Marketing Approval Date:	11/17/2022
Approved Labeled Indication:	treatment of neonatal seizures in term and preterm infants
Exclusivity End Date:	11/17/2029
Exclusivity Protected Indication* :	treatment of neonatal seizures in term and preterm infants

*Exclusivity Protected Indications are shown for approvals from 01/01/2013 to the present.

*Data for the Date Designation Withdrawn or Revoked field are shown for designations withdrawn or revoked after 08/12/2013.

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