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Generic Name: diazoxide choline
Trade Name: Vykate XR
Date Designated: 05/13/2014
Orphan Designation: Treatment of Prader-Willi Syndrome
Orphan Designation Status: Designated/Approved
Solenio Therapeutics, Inc.
100 Marine Parkway, Suite 400
Redwood City, California 94065
Sponsor: United States
The sponsor address listed is the last reported by the sponsor to OOPD.

Marketing approved:

1 **Generic Name:** diazoxide choline
Trade Name: Vykate XR
Marketing Approval Date: 03/26/2025
Approved Labeled Indication: treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS)
Exclusivity End Date: 03/26/2032
Exclusivity Protected Indication* : treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS)

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*Data for the Date Designation Withdrawn or Revoked field are shown for designations withdrawn or revoked after 08/12/2013.

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U.S. Food and Drug Administration

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