Supporting patients during treatment

with proactive monitoring and dose adjustments

VYKAT™ XR (diazoxide choline) extended-release tablets

Monitoring for potential hyperglycemia and fluid overload is important during treatment with VYKAT™ XR. The following recommendations may help as you support your patients.

Monitor and optimize blood glucose before starting and throughout treatment

Before initiating VYKAT XR	After initiating VYKAT XR
• Test fasting plasma glucose (FPG) and HbA1c • Optimize blood glucose in patients who have hyperglycemia	**Fasting glucose** **Weeks 1-2:** Monitor fasting glucose (FPG or fasting blood glucose) at least once a week and as clinically indicated **Weeks 3 and ongoing:** Monitor fasting glucose (FPG or fasting blood glucose) at least once every 4 weeks and as clinically indicated **HbA1c** Monitor HbA1c every 3 months and as clinically indicated

Fasting blood glucose may be measured at home with a blood glucose meter at the discretion of the treating physician and patient.

Optimize blood glucose in patients who have hyperglycemia

- Monitor fasting glucose more frequently during the first few weeks of treatment in patients with risk factors for hyperglycemia
- Patients with type 2 diabetes were allowed to enroll in the clinical trials for VYKAT XR if they were adequately managed with a stable dose of antidiabetic medications for ≥3 months[1]

HbA1c, hemoglobin A1c.

INDICATION

VYKAT XR is indicated for the treatment of hyperphagia in adults and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS).

SELECT IMPORTANT SAFETY INFORMATION

Contraindications

Use of VYKAT XR is contraindicated in patients who have a known hypersensitivity to diazoxide, other components of VYKAT XR, or to thiazides.

Please see Important Safety Information throughout and full Prescribing Information, including Medication Guide.

Dose adjustments may be necessary for patients with hyperglycemia or fluid overload

If hyperglycemia is observed before or during treatment	• Temporarily interrupt VYKAT XR or reduce the dose until glycemic parameters are appropriately managed • If clinically significant glucose elevations are noted, titrate over a longer duration and/or to a lower dosage • Consider initiation or adjustment of standard antidiabetic therapy(ies)
If fluid overload is observed before or during treatment	• If clinically significant fluid overload is noted, titrate over a longer duration and/or to a lower dosage • Consider appropriate clinical management, which may include dosage reduction or temporary dosage interruption in the event of clinically significant fluid overload
When either are resolved	• Titrate the dose in small increments, no greater than 25 mg for patients weighing <30 kg, and 75 mg for patients weighing ≥30 kg every 2 weeks or titrate over a longer duration to a maximum of 5.8 mg/kg/day • Daily doses ≥525 mg, or above 5.8 mg/kg/day, have not been evaluated in patients with PWS

Please see VYKAT XR Prescribing Information Section 2.3 for guidance on monitoring and dosage modifications due to adverse reactions.

IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and Precautions

Hyperglycemia

Hyperglycemia, including diabetic ketoacidosis, has been reported. Before initiating VYKAT XR, test fasting plasma glucose (FPG) and HbA1c; optimize blood glucose in patients who have hyperglycemia. During treatment, regularly monitor fasting glucose (FPG or fasting blood glucose) and HbA1c. Monitor fasting glucose more frequently during the first few weeks of treatment in patients with risk factors for hyperglycemia.

Risk of Fluid Overload

Edema, including severe reactions associated with fluid overload, has been reported. Monitor for signs or symptoms of edema or fluid overload. VYKAT XR has not been studied in patients with compromised cardiac reserve and should be used with caution in these patients.

Adverse Reactions

The most common adverse reactions (incidence ≥10% and at least 2% greater than placebo) included hypertrichosis, edema, hyperglycemia, and rash.

Drug Interactions

Concomitant use of VYKAT XR with strong CYP1A2 inhibitors increases exposure of diazoxide. Reduce VYKAT XR dosage with strong CYP1A2 inhibitors. Concomitant use of VYKAT XR is not recommended with CYP1A2 substrates due to increased exposure of these substrates. Concomitant use of VYKAT XR is not recommended with dual strong CYP3A4/moderate CYP1A2 inducers due to decreased exposure of VYKAT XR. Diazoxide is highly bound to serum proteins and may displace other drugs that are also highly bound to protein of which impact is expected to be clinically important for narrow therapeutic index drugs; monitor INR with coumarin or its derivatives and monitor diphenylhydantoin serum levels and adjust dose if needed when used concomitantly with VYKAT XR. Concomitant use of VYKAT XR with thiazides or other diuretics may potentiate hyperglycemic and hyperuricemic effects; dose adjustment of VYKAT XR or diuretics may be needed.

To report SUSPECTED ADVERSE REACTIONS, contact Soleno Therapeutics, Inc. at 1-833-765-3661 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reference: 1. Data on file, Soleno Therapeutics, Inc.

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SOLENO THERAPEUTICS

C-US-VYK-00272 v2 12/2025

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