



A Letter to the Prader-Willi Syndrome Community

March 26, 2026

Dear members of the Prader-Willi syndrome community,

One year ago, VYKAT™ XR (diazoxide choline) was approved in the United States as the first FDA-approved treatment for hyperphagia in people ages 4 and older living with Prader-Willi syndrome (PWS). For Soleno, this milestone marks more than an anniversary of our approval. It marks the responsibility of delivering on a commitment we made to this community over a decade ago.

On behalf of the entire Soleno team, thank you for trusting us and for allowing us to walk alongside you during this first year.

From the beginning, we recognized that PWS is a complex, lifelong condition with many interconnected symptoms and comorbidities. Among them, hyperphagia, a chronic and life-threatening feeling of intense, persistent hunger that cannot be satisfied by food, stands apart not as just one feature, but as the most urgent and defining challenge. It often shapes daily life, safety, independence, and long-term outcomes for individuals and families. Where others saw overwhelming complexity, we saw a calling. That conviction continues to guide how we listen, how we act, and how we show up for this community.

What has the first year reinforced for us?

This past year has reinforced a truth, long understood by families and individuals living with hyperphagia associated with PWS: there is no single experience of this condition, and no single measure of progress. Hyperphagia affects individuals and families in deeply personal ways, and meaningful change must be understood in the context of daily life, not just clinical milestones.

We have learned that progress is built through partnership – between individuals, caregivers, healthcare providers, advocates, and the broader rare disease community. Our role is to ensure families have access to a treatment option backed by science and approved for use by the FDA, alongside the education and support needed to make informed decisions.

How is VYKAT being used today?

Since approval, VYKAT XR has been prescribed across a broad range of patients 4 years and older experiencing different stages of life, reflecting the diverse hyperphagia with PWS population. Families and clinicians have approached treatment thoughtfully, recognizing that responses vary and that each individual's journey is unique. We are proud to share that over 850 individuals are on treatment with VYKAT XR.

We remain committed to transparency as we continue to learn from real-world experience and the questions our dedicated Patient and Community Educators (PACE) team is receiving every day. Their role is simple but meaningful: helping people feel informed, supported, and more confident as they navigate their journey. Families and caregivers often share that they are committed and hopeful as they continue to monitor changes over time. Open dialogue with healthcare providers, careful monitoring, and individualized care remain essential components of treatment decision-making.

Please see pages 2 and 3 for Important Safety Information for VYKAT XR.

What are caregivers telling us about VYKAT XR?

Caregivers have shared how managing hyperphagia in PWS often extends far beyond food control. Some have described changes that feel meaningful in daily life; others continue to face challenges that require ongoing support and adjustment.

These perspectives matter. Caregiver insight is not supplemental to science; it strengthens it. Listening to families remains central to how we understand impact and how we continue to evolve our approach.

What remains important to understand about safety and ongoing care for those receiving VYKAT XR under the care of their physician?

Hyperphagia associated with PWS is a complex, multi-system condition, and responses to treatment can differ. Families considering or using VYKAT XR should continue to work closely with their healthcare providers to determine what is appropriate for their individual situation.

Soleno is committed to earning trust through transparency by communicating clearly, sharing safety information responsibly, and holding ourselves to the highest standards of monitoring and accountability.

For individuals that are interested in learning more about VYKAT XR, we encourage you to start with your trusted healthcare provider by sharing how untreated hyperphagia impacts you or your loved one's daily life.

For more information, including the Full Prescribing Information, Medication Guide, and Important Safety Information, visit www.vykatxr.com/ and sign up for updates, including opportunities to join educational webinars, at www.vykatxr.com/sign-up

How is Soleno supporting the rare disease and Prader-Willi syndrome community beyond treatment?

Our commitment extends beyond a prescription. Over the past year, we have continued to invest in education, community support resources, and partnerships with rare disease advocacy organizations. We aim to ensure families have access to clear information, support navigating coverage, and trusted points of connection throughout their journey.

Just as important, we remain deeply engaged with the community. Your voices guide how we grow, how we prioritize, and how we remain accountable to the people we serve.

One year in, we are focused.

Our journey began with PWS, and our responsibility to this community remains at the center of everything we do. We will continue to advance care, support education and awareness, and work toward a future where individuals living with PWS have more options, greater understanding, and sustained support across their lifetimes.

Thank you for allowing us to be part of this journey and for holding us to the standard this community deserves

Please see below for Important Safety Information for VYKAT XR.

With gratitude,
The Soleno Therapeutics Team

IMPORTANT SAFETY INFORMATION

What is VYKAT XR used for?

VYKAT XR is a prescription medicine used to treat extreme hunger, constant thoughts about food, and constant urge to eat that cannot be satisfied with food (hyperphagia) in adults and children 4 years of age and older with Prader-Willi syndrome (PWS).

What is the most important information I should know about VYKAT XR?

VYKAT XR may cause serious side effects, including:

- **High blood sugar levels (hyperglycemia).** Hyperglycemia is common during treatment with VYKAT XR and can also be severe. Hyperglycemia can lead to a condition called diabetic ketoacidosis (increased ketones in the blood) in some people who take VYKAT XR. Diabetic ketoacidosis is a serious condition that needs to be treated in a hospital and can be life-threatening

Please see page 3 for additional Important Safety Information for VYKAT XR.

- Your healthcare provider will:
 - check your blood sugar levels before you start VYKAT XR, during treatment and more often during treatment if you have an increased chance of getting hyperglycemia.
 - check your HbA1c before and during treatment.
- If you get hyperglycemia during treatment with VYKAT XR, your healthcare provider may give you medicines to treat hyperglycemia, change your dose if you already take hyperglycemia medications, or your doctor may change your dose of, temporarily stop, or permanently stop VYKAT XR.

Tell your healthcare provider if you get any of the following signs and symptoms:

- **hyperglycemia:** feel very thirsty, need to urinate more often than usual, have higher amounts of urine than usual, feel more hungry than usual, or weight loss
 - **diabetic ketoacidosis:** nausea, vomiting, stomach-area (abdominal) pain, feel weak or very tired or trouble breathing
- **Too much fluid in your body or swelling (fluid overload).** Swelling in the body from too much fluid is common during treatment with VYKAT XR and can also be severe. Your healthcare provider may decrease your dose or temporarily stop VYKAT XR if you get fluid overload. Tell your healthcare provider if you have trouble breathing or get any other signs or symptoms of fluid overload such as swelling of your legs, ankles, or feet, or unusual swelling anywhere in your body.

Who should NOT take VYKAT XR?

Do not take VYKAT XR if you are allergic to diazoxide, any ingredients in VYKAT XR or medicines called thiazides.

Before taking VYKAT XR, tell your healthcare provider about all of your medical conditions, including if you:

- have diabetes or prediabetes
- are sick
- plan to have surgery
- drink alcohol very often
- are dehydrated or have lost a lot of body fluid
- have heart problems or a history of swelling in your legs or other parts of your body that required medicine
- have liver or kidney problems
- are pregnant or plan to become pregnant. VYKAT XR may harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with VYKAT XR
- are breastfeeding or plan to breastfeed. VYKAT XR passes into your breast milk, and it is not known if it can harm your baby. Tell your healthcare provider if you plan to breastfeed during treatment with VYKAT XR

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking VYKAT XR with certain other medicines may affect the way VYKAT XR or the other medicine works and may increase your risk of side effects. **Do not** change your dose or stop any medicines you take, or start any new medicines, without talking to your healthcare provider first during treatment with VYKAT XR.

What are the possible side effects of VYKAT XR?

Increased hair growth all over the body, fluid overload or swelling, high blood sugar levels, and rash.

These are NOT all of the possible side effects of VYKAT XR.

Call your doctor for medical advice about side effects. You may report side effects to Soleno Therapeutics, Inc. at 1-833-765-3661 or to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For further information please read the Medication Guide and full Prescribing Information for VYKAT XR.


v y k a t™ **X R**
 (diazoxide choline) extended-release tablets

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