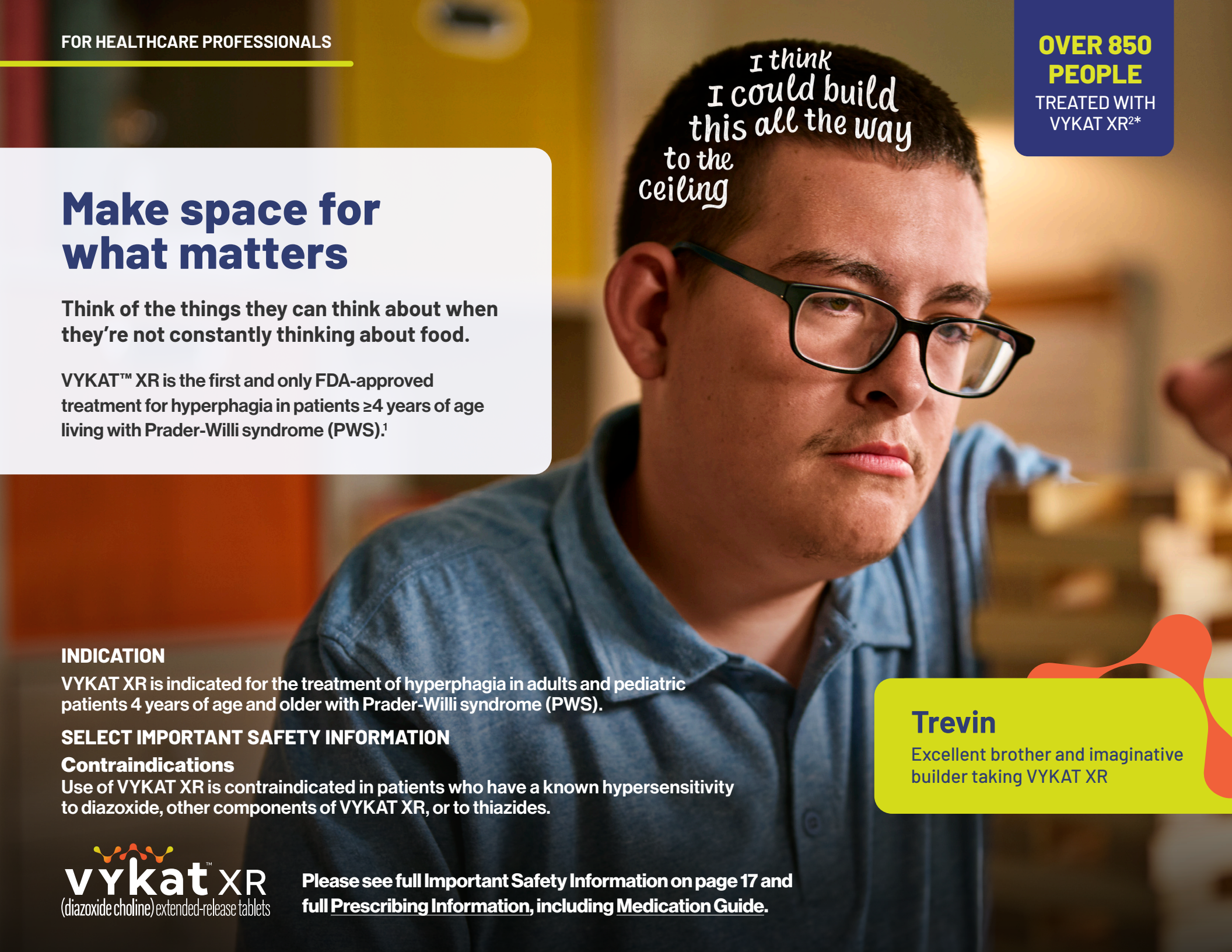
FOR HEALTHCARE PROFESSIONALS

Make space for what matters

Think of the things they can think about when they're not constantly thinking about food.

VYKAT™ XR is the first and only FDA-approved treatment for hyperphagia in patients ≥4 years of age living with Prader-Willi syndrome (PWS).[1]



OVER 850 PEOPLE
TREATED WITH VYKAT XR[2]*

Trevin
Excellent brother and imaginative builder taking VYKAT XR

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.

vykat™ XR
(diazoxide choline) extended-release tablets

Please see full Important Safety Information on page 17 and full Prescribing Information, including Medication Guide.

Managing hyperphagia in PWS is more than just managing weight[3-5]

Hyperphagia can initially present more subtly as food preoccupation in early childhood. Over time, hyperphagia becomes more pronounced and persists throughout life.[6-9]

Food preoccupation[7,10]:

- Spending time thinking, talking about, or asking for food
- Feeling distressed if told to stop asking about food
- Food-related interruptions in daily activities

Drive to consume food[7]:

- Bargaining to get more food
- Trying to steal food
- Foraging through trash for food
- Getting up at night to food seek

Food-related behavior problems[7]:

- Getting upset when denied food
- Persistently asking for food after being told no

Lack of satiety[7]:

- Consuming a significantly excessive amount of calories
- Overeating to the point of gastric rupture or necrosis

SELECT IMPORTANT SAFETY INFORMATION

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.

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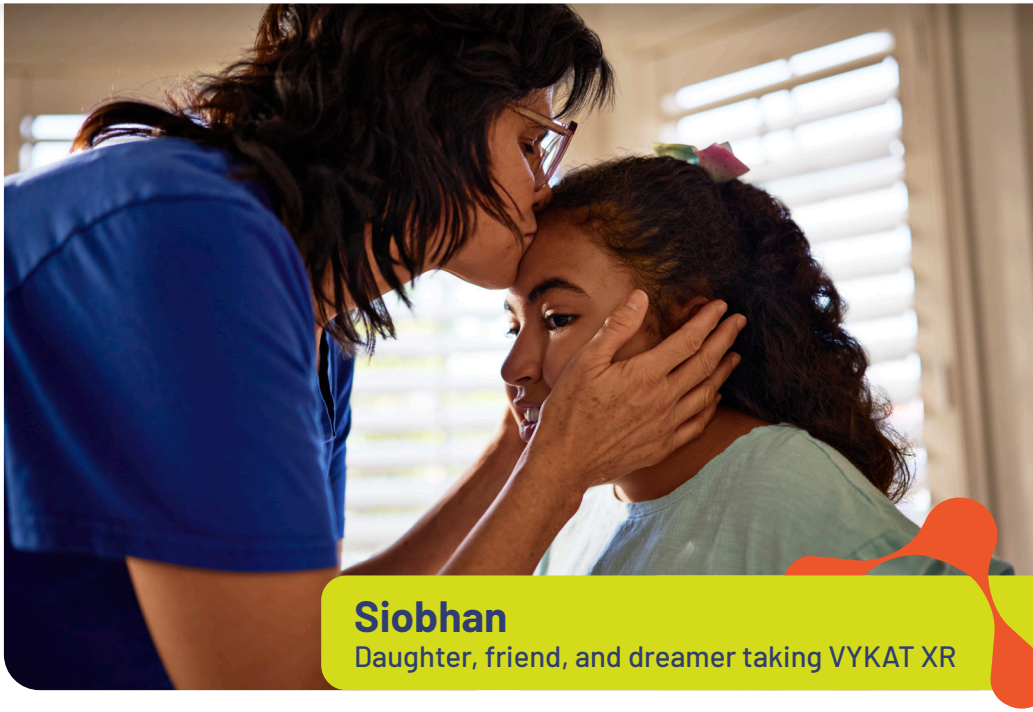
Even when weight appears to be managed and environmental controls are in place, patients may still be burdened by hyperphagia[3]

Hyperphagia in PWS often prevents full participation in school, employment, social life, and independent living[11-14]

Hyperphagia affects everyone differently and the burden impacts every aspect of life for individuals with PWS and their caregivers[3,7,12,14]



Siobhan
Daughter, friend, and dreamer taking VYKAT XR

SELECT IMPORTANT SAFETY INFORMATION

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.

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Efficacy was measured by mean change in HQ-CT Total Score[14,15]

The Hyperphagia Questionnaire for Clinical Trials (HQ-CT) is a validated, 9-item, caregiver-completed instrument designed for use in clinical studies[14,15]

The instrument was designed to assess a range of hyperphagia behaviors during the prior 2 weeks.[14]

Each of the 9 items was graded 0 to 4, with Total Score ranging from 0 to 36.[14]

The instrument was completed consistently by the same caregiver in each study.[14]

A lower HQ-CT Total Score indicated less severe hyperphagia.

SELECT IMPORTANT SAFETY INFORMATION

Contraindications
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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.

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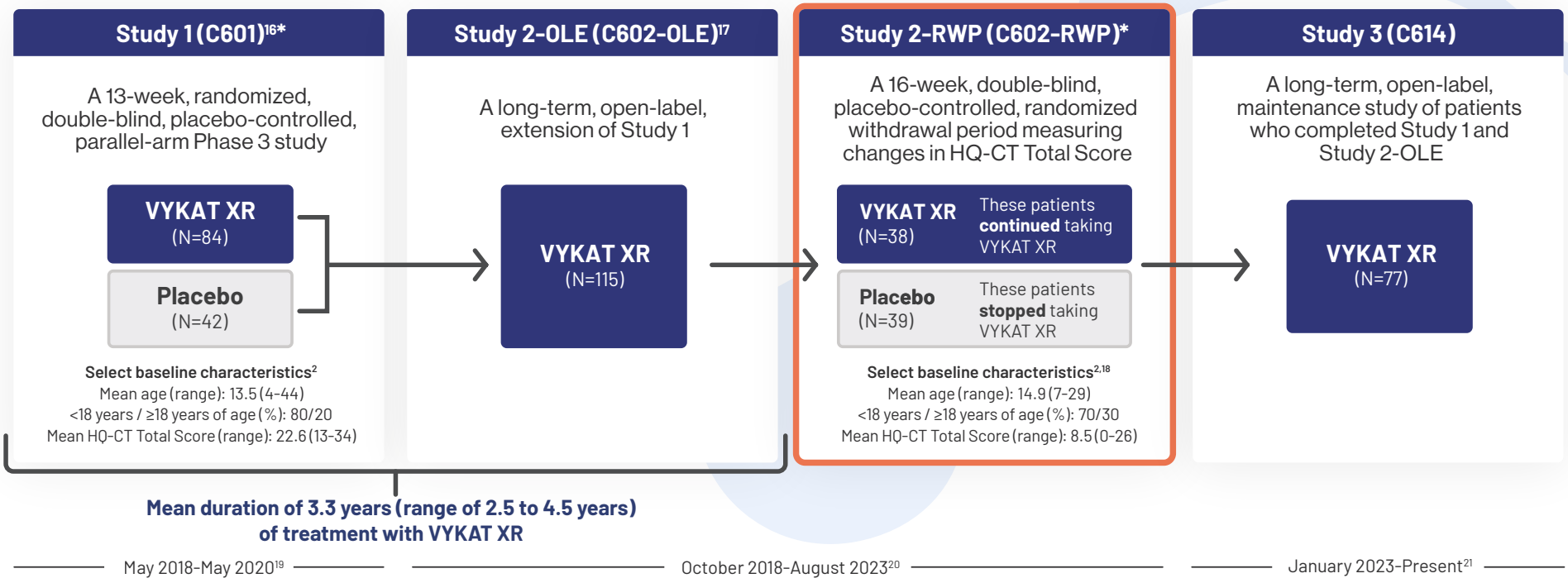
VYKAT XR was studied for over 4 years in clinical trials of adults and pediatric patients



Please note: Study 1 primary endpoint did not meet statistical significance. COVID-19 may have been a factor that contributed to missing data in Study 1. 31% of patients (N=38) who had at least 1 post-baseline assessment of HQ-CT (N=124) experienced interrupted visits.[16]

*Patients in Study 1 were randomized in a 2-to-1 ratio and patients in Study 2-RWP were randomized in a 1-to-1 ratio.

COVID-19, SARS-CoV-2 2019; OLE, open-label extension; RWP, randomized withdrawal period.

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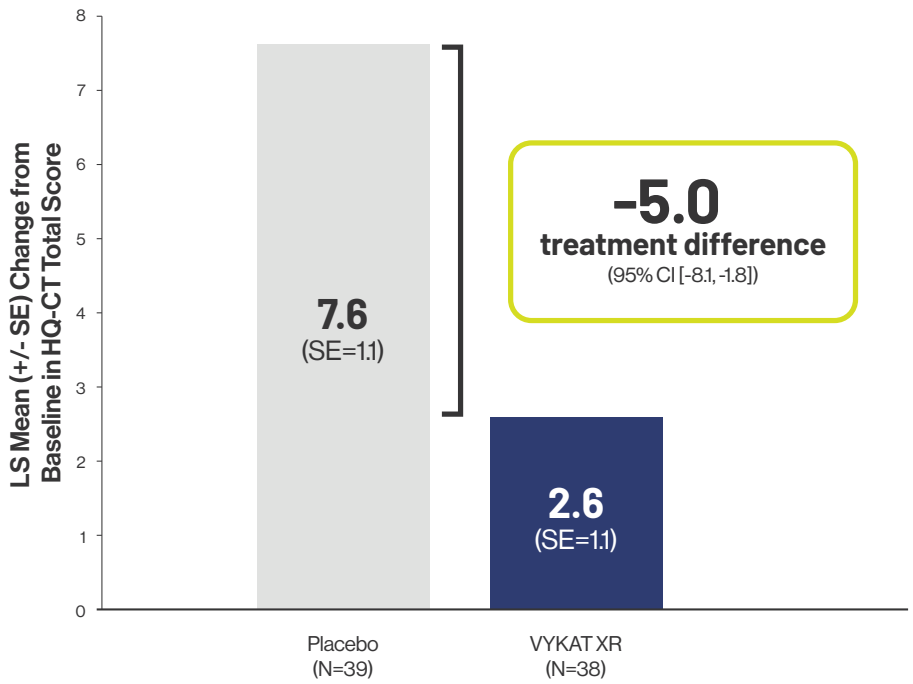
STUDY
2-RWP

Patients who continued VYKAT XR had less hyperphagia vs placebo at the end of the randomized withdrawal period[2]

HQ-CT Total Score Change at Week 16



Patients randomized to placebo had statistically significant worsening of hyperphagia vs those who continued taking VYKAT XR

- Study 2-RWP included 77 patients who completed Study 2-OLE. All patients entering the study had completed 2.5-4.5 years of treatment with VYKAT XR
- In Study 2-RWP, the mean baseline HQ-CT Total Score for patients taking VYKAT XR vs placebo was 9.0 and 8.1, respectively
- A lower HQ-CT Total Score indicated less severe hyperphagia

LS, least squares; SE, standard error.

SELECT IMPORTANT SAFETY INFORMATION

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.

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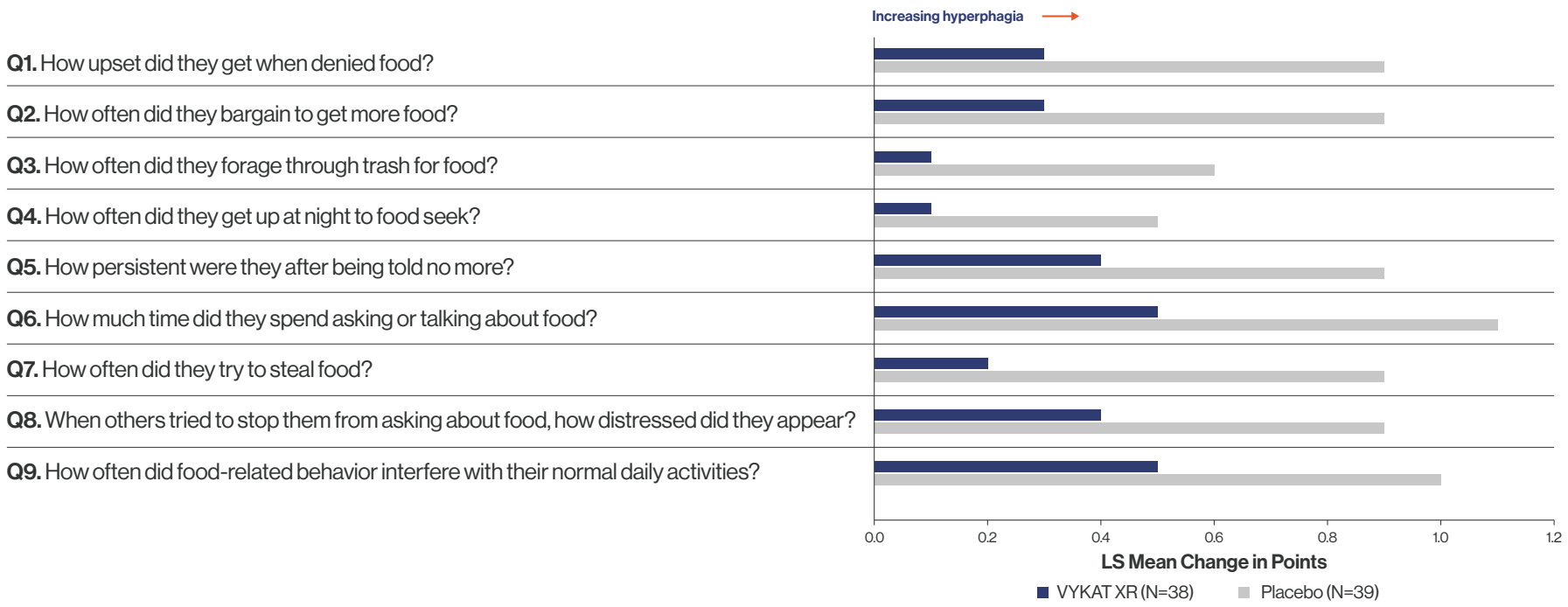
STUDY
2-RWP

Changes were observed across all questions of the HQ-CT with VYKAT XR vs placebo[2,18]

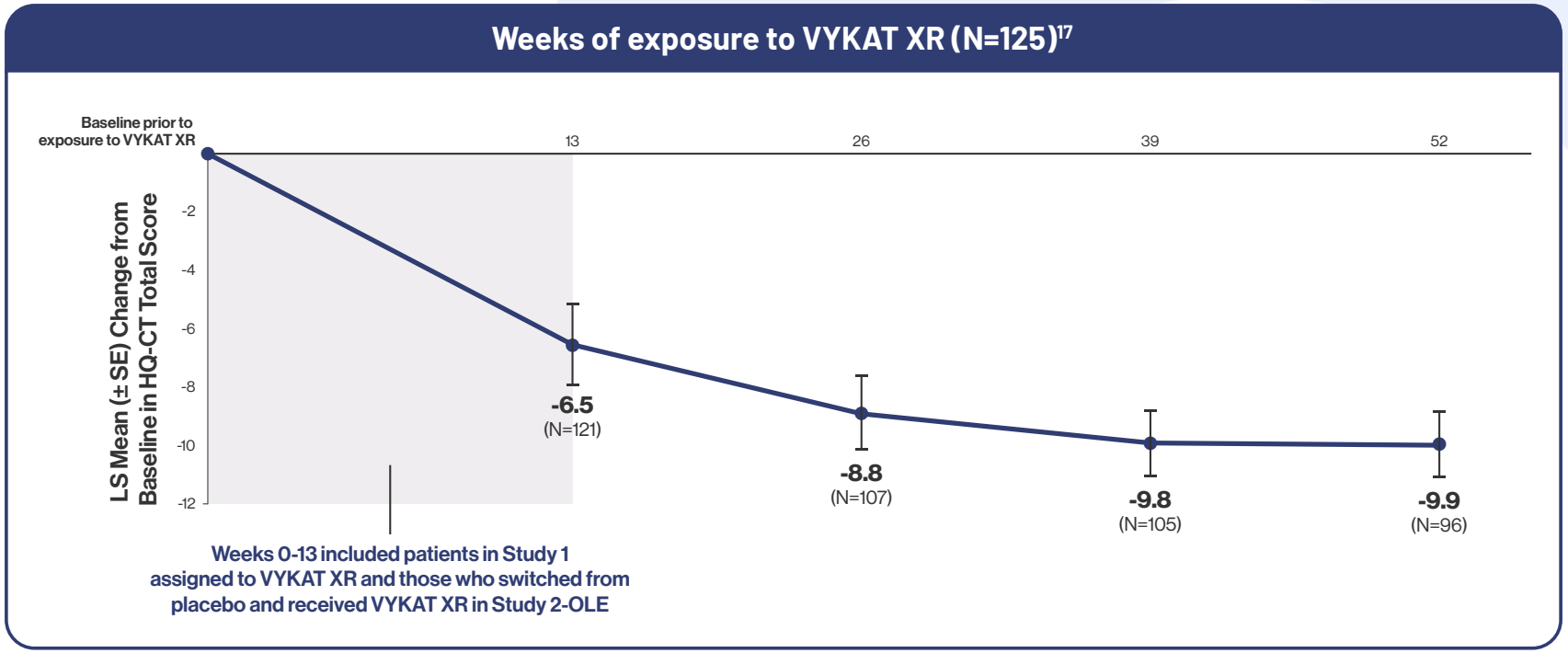
HQ-CT item changes from baseline at Week 16 in Study 2-RWP[2,18]



Consider what a change in hyperphagia could mean for your patients with PWS

STUDIES
1+2-OLE

Patients from Study 1 who continued VYKAT XR or switched from placebo had reductions in their Study 2-OLE HQ-CT Total Score[17]



Study 2-OLE was a long-term, open-label extension study in 115 patients from Study 1. This study was uncontrolled and subject to bias and other factors that may limit applicability and conclusions.[17]

Set expectations around when patients can expect to see efficacy with VYKAT XR to ensure adherence at the start and throughout treatment

SELECT IMPORTANT SAFETY INFORMATION

Contraindications
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Ben
Ultimate fetch partner taking VYKAT XR

Patients taking VYKAT XR should continue with their routines for managing hyperphagia[3-5]

- Environmental controls, behavioral management, and nutrition optimization are key to continuous management of hyperphagia[4,5]
- VYKAT XR can be taken with the diet plan that works best for your patients

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The safety profile of VYKAT XR was established over 4 years[17,18]

Adverse reactions occurring in ≥5% of patients with VYKAT XR and ≥2% greater than placebo in Study 1*

Adverse Reaction	VYKAT XR (N=84)	Placebo (N=42)
Hypertrichosis	**36%**	14%
Edema†	**27%**	12%
Hyperglycemia‡	**17%**	5%
Rash§	**12%**	2%
Pyrexia	**6%**	0%
Arthralgia	**5%**	2%
Influenza	**5%**	2%
Nasopharyngitis	**5%**	2%

The primary safety analyses were based on Study 1, a randomized, placebo-controlled trial designed to assess the efficacy and safety of VYKAT XR

For additional safety data from Study 2-RWP and Study 3, see the full Prescribing Information.

Learn about monitoring and dose adjustments for hyperglycemia and fluid overload on pages 13-15

*Erythema multiforme was reported in one patient in Study 1. One patient in Study 3 experienced a serious adverse reaction of diabetic ketoacidosis.
†Edema includes peripheral edema, periorbital edema, swelling face, pulmonary edema, and peripheral swelling.
‡Hyperglycemia includes type 2 diabetes mellitus.
§Rash includes contact dermatitis, erythema multiforme, maculo-papular rash, papular rash, and urticaria.

VYKAT XR offers convenient once-daily oral dosing based on weight

VYKAT XR tablets are available in the following strengths

VYKAT XR 25 mg		12.9 mm
VYKAT XR 75 mg		8.6 mm
VYKAT XR 150 mg		15.3 mm
Green Pea For size comparison only		9 mm

VYKAT XR can be taken with or without food

- The maximum recommended dose of VYKAT XR is 5.8 mg/kg/day or 525 mg per day
- Advise patients to swallow tablets whole. Do not split, crush, or chew tablets

Please see full Important Safety Information on page 17 and full Prescribing Information, including Medication Guide.

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VYKAT XR is administered using a weight-based titration schedule to help mitigate the occurrence and severity of adverse events

VYKAT XR recommended once-daily dosage

Weight	Starting Dosage Weeks 1 and 2	Titration Dosage Weeks 3 and 4	Titration Dosage Weeks 5 and 6	Target Maintenance Dose
20-<30 kg	25 mg	50 mg	75 mg	**100 mg**
30-<40 kg	75 mg	150 mg	150 mg	**150 mg**
40-<65 kg	75 mg	150 mg	225 mg	**225 mg**
65-<100 kg	150 mg	225 mg	300 mg	**375 mg**
100-<135 kg	150 mg	300 mg	375 mg	**450 mg**
≥135 kg	150 mg	300 mg	450 mg	**525 mg**

Refer to the Prescribing Information for guidance on required dose adjustments for concomitant use with strong CYP1A2 inhibitors.

Discontinuation or interruption of treatment

Treatment with VYKAT XR can be discontinued without tapering.

Following a dose interruption or missed dose of:

- Less than 7 days, resume VYKAT XR at the previous dose
- 7 days or more, re-titrate VYKAT XR when resumed according to the dosing table

Please see full Important Safety Information on page 17 and full Prescribing Information, including Medication Guide.

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Proactive monitoring and dose adjustments can support patients during treatment

Monitor and optimize blood glucose before starting and throughout treatment

Hyperglycemia

Monitor fasting glucose more frequently during the first few weeks of treatment in patients with risk factors for hyperglycemia.

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

HbA1c, hemoglobin A1c.

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

SELECT IMPORTANT SAFETY INFORMATION

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.

Please see full Important Safety Information on page 17 and full Prescribing Information, including Medication Guide.

Monitor for clinically significant elevations in fasting glucose or HbA1c before starting and throughout treatment

If 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)

When 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

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Monitor for fluid overload before starting and throughout treatment, and consider appropriate management of patients

If 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 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

Support one step at a time

SOLENO one™

Patient support that's comprehensive and complementary to your care. That's Soleno One™

For patients who have been prescribed VYKAT XR, our program combines personalized education and tools to support patients in starting and continuing treatment.

Soleno One™ assists patients with:

- Step-by-step support for their VYKAT XR prescription
- Benefits verification and product access education
- Exploring financial support, including potential co-pay assistance for eligible patients and caregivers
- One-on-one support for them and their caregivers

Soleno One™ can also support with:

- Ongoing education for your staff
- Collaboration with your office to ensure patients have access to necessary resources
- Educating your staff on the reimbursement and specialty pharmacy processes

Prescribe today with Soleno One™
Scan the QR code to download Rx Start Form

Important Safety Information

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).

IMPORTANT SAFETY INFORMATION

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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.

Please see the full Prescribing Information, including Medication Guide.

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References

1. Soleno Therapeutics announces U.S. FDA approval of VYKAT™ XR to treat hyperphagia in Prader-Willi syndrome. News Release. Soleno Therapeutics. March 26, 2025. Accessed May 7, 2026. https://investors.soleno.life/news-releases/news-release-details/soleno-therapeutics-announces-usfda-approval-vykattm-xr-treat **2.** Data on file, Soleno Therapeutics, Inc. **3.** Heymsfield SB, Avena NM, Baier L, et al. Hyperphagia: current concepts and future directions proceedings of the 2nd international conference on hyperphagia. *Obesity (Silver Spring)*. 2014;22 Suppl 1(0 1):S1-S17. **4.** Miller JL, Tan M. Dietary management for adolescents with Prader-Willi syndrome. *Adolesc Health Med Ther.* 2020;11:113-118. **5.** Ho AY, Dimitropoulos A. Clinical management of behavioral characteristics of Prader-Willi syndrome. *Neuropsychiatr Dis Treat*. 2010;6:107-118. **6.** Tauber M, Hoybye C. Endocrine disorders in Prader-Willi syndrome: a model to understand and treat hypothalamic dysfunction. *Lancet Diabetes Endocrinol.* 2021;9(4):235-246. **7.** Schwartz L, Caixàs A, Dimitropoulos A, et al. Behavioral features in Prader-Willi syndrome (PWS): consensus paper from the International PWS Clinical Trial Consortium. *J Neurodev Disord.* 2021;13(1):25. **8.** Miller JL, Lynn CH, Driscoll DC, et al. Nutritional phases in Prader-Willi syndrome. *Am J Med Genet A.* 2011;155A(5):1040-1049. **9.** Kotler J, Balko K, Berall G, et al. Nutritional phases in Prader-Willi syndrome: evolutionary and clinical interpretations. *J Evolutionary Med.* 2016;(4):1-7. doi:10.4303/jem/235968 **10.** Dykens EM, Maxwell MA, Pantino E, et al. Assessment of hyperphagia in Prader-Willi syndrome. *Obesity (Silver Spring)*. 2007;15(7):1816-1826. **11.** Cassidy SB, Schwartz S, Miller JL, et al. Prader-Willi syndrome. *Genet Med.* 2012;14(1):10-26. **12.** Driscoll DJ, Miller JL, Cassidy SB. Prader-Willi Syndrome. In: Adam MP, Feldman J, Mirzaa GM, Pagon RA, Wallace SE, Amemiya A, eds. *GeneReviews®*. Seattle (WA): University of Washington, Seattle; October 6, 1998. **13.** Bedard KE, Pacha D, Griffith AK, et al. Prader-Willi syndrome: a primer for school psychologists. *Child Youth Services Rev.* 2024;163:1- 7. **14.** Matesevac L, Vrana-Diaz CJ, Bohonowych JE, et al. Analysis of hyperphagia questionnaire for clinical trials (HQ-CT) scores in typically developing individuals and those with Prader-Willi syndrome. *Sci Rep.* 2023;13:20573. **15.** Fehnel S, Brown M, Nelson L, et al. Development of the hyperphagia questionnaire for use in Prader-Willi syndrome clinical trials. Poster. Presented at ISPOR 20th Annual International Meeting; May 16-20, 2015; Philadelphia, PA. **16.** Miller JL, Gevers E, Bridges N, et al. Diazoxide choline extended-release tablet in people with Prader-Willi syndrome: a double-blind, placebo-controlled trial. *J Clin Endocrinol Metab.* 2023;108(7):1676-1685. **17.** Miller JL, Gevers E, Bridges N, et al. Diazoxide choline extended-release tablet in people with Prader-Willi syndrome: results from long-term open-label study. *Obesity (Silver Spring)*. 2024;32(2):252-261. **18.** Gevers EF, Miller JL, Bridges NA, et al. Withdrawal of diazoxide choline extended-release (DCCR) tablets worsens hyperphagia and increases weight and BMI in a 16-week, double-blind, placebo-controlled, randomized withdrawal period in patients with Prader-Willi syndrome. Presented at ENDO 2024; June 1-4, 2024; Boston, MA. **19.** A study of diazoxide choline in patients with Prader-Willi syndrome. ClinicalTrials.gov identifier: NCT03440814. Updated September 21, 2023. Accessed May 7, 2026. https://clinicaltrials.gov/study/NCT03440814 **20.** Open-label extension study of DCCR in PWS followed by double-blind, placebo-controlled, randomized withdrawal period. ClinicalTrials.gov identifier: NCT03714373. Updated April 19, 2024. Accessed May 7, 2026. https://clinicaltrials.gov/study/NCT03714373 **21.** Open-label extension study of DCCR in patients with Prader-Willi syndrome. ClinicalTrials.gov identifier: NCT05701774. Updated April 4, 2024. Accessed May 7, 2026. https://clinicaltrials.gov/study/NCT05701774

*Data as of December 2025.[2]

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Make space for what matters

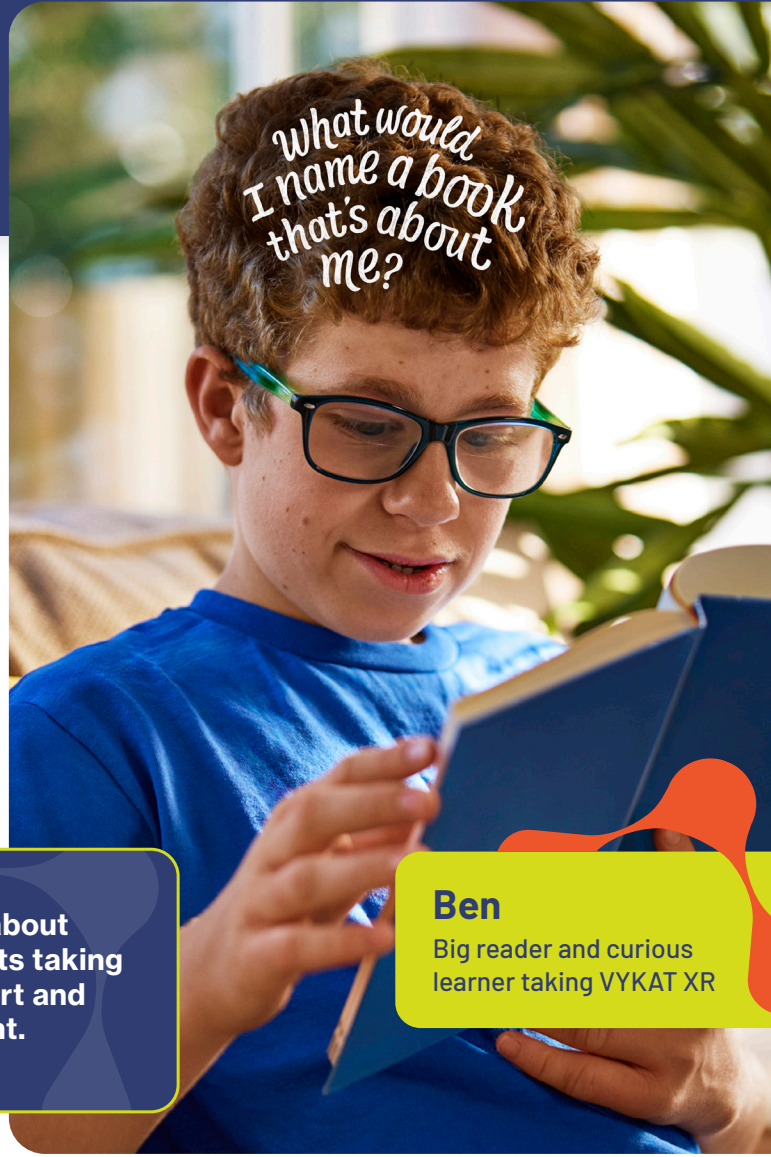
With the first and only FDA-approved treatment for hyperphagia in PWS[1]

- **Even when weight appears to be managed and environmental controls are in place, patients may still be burdened by hyperphagia[3]**
- **Patients who continued VYKAT XR had less hyperphagia vs placebo at the end of the 16-week randomized withdrawal period[2]**

  Patients randomized to placebo had statistically significant worsening of hyperphagia vs those who continued taking VYKAT XR.
- **VYKAT XR reduced hyperphagia over 52 weeks in patients who continued from Study 1 into Study 2-OLE, including those who previously received placebo[17]**
- **VYKAT XR offers convenient, once-daily oral dosing with a weight-based titration schedule**
- **Safety profile established over 4 years of treatment[17,18]**

  In Study 1, the most common adverse reactions (≥10% and ≥2% than in placebo) were hypertrichosis, edema, hyperglycemia, and rash.

Scan to learn more about resources for patients taking VYKAT XR at the start and throughout treatment.



Ben
Big reader and curious learner taking VYKAT XR

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SOLENO THERAPEUTICS

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