

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 people ages 4 and older living with Prader-Willi syndrome (PWS).

What would I name a book that's about me?

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).

Ben

Big reader and curious learner taking VYKAT XR


vykat XR
(diazoxide choline) extended-release tablets

Please see additional Important Safety Information throughout and full Prescribing Information, including Medication Guide, for VYKAT XR.

Hyperphagia looks different for everyone, but most people with PWS will experience it

Get to know the different sides of hyperphagia

Hyperphagia is a common symptom of PWS. Hyperphagia is known as extreme hunger, constant thoughts about food, and a constant urge to eat that cannot be satisfied with food, but there is more to hyperphagia than you may know.



Hyperphagia can start as early as age 4 and often continues throughout life for people living with PWS.



People with PWS and hyperphagia **aren't always obese or overweight.**



Hyperphagia can also mean food-related anxiety or **constantly thinking and talking about food**, but may not always mean overeating.



A change in routine, even due to seasonal changes, can **affect people with PWS who have hyperphagia.**

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What are the signs of hyperphagia?

Obsessive thoughts about food

- Obsessively talks about food or asks for food
- Gets upset when stopped from talking about food

Greater urge to eat

- Bargains and manipulates others to get food
- Gets upset when denied food

Behavioral problems related to food

- Forages through trash for food
- Sneaks food while family is asleep
- Wakes up in the middle of the night to pursue and sneak food

Rarely feels full

- Eats excessively or to the point of dangerous stomach problems

The early signs of hyperphagia may be hard to recognize.

Environmental controls and other routines may make symptoms even less obvious.

That's why it's important to talk to your doctor about hyperphagia throughout the PWS journey

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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Hyperphagia can change over time, from childhood to adulthood



Children ages 4 and older

Children with hyperphagia start to **show a strong interest in food** and can start to **ask a lot of questions about food**.



Adolescents and teens

As hyperphagia continues, people living with it can **feel hungry all the time** and may start to ask about food a lot. When denied food, **they can become upset**.

As people with hyperphagia age, they could start to **manipulate others for food** and **sneak or steal food**.



Adults

Hyperphagia **continues throughout life** and people living with it need **ongoing, constant supervision**.

More than 60 years after PWS was first described, an FDA-approved treatment option for hyperphagia is available

IMPORTANT SAFETY INFORMATION (CONT'D)

VYKAT XR may cause serious side effects, including high blood sugar levels (hyperglycemia) (cont'd)

- 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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

VYKAT XR can help manage extreme hunger, constant thoughts about food, and a constant urge to eat that cannot be satisfied with food

IMPORTANT SAFETY INFORMATION (CONT'D)

VYKAT XR may cause serious side effects, including high blood sugar levels (hyperglycemia) (cont'd)

- 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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

Klara

Proud triathlete and loving daughter taking VYKAT XR

VYKAT XR was studied in a range of people living with PWS and hyperphagia

The effect of VYKAT XR on hyperphagia and food-related behaviors was measured using a caregiver survey

The impact of VYKAT XR on hyperphagia was studied in clinical trials where people were on treatment for 2.5 to 4.5 years. In the main clinical trial, half of the people in the trial were randomly selected to stop taking VYKAT XR and take placebo (a sugar pill) for 16 weeks. The other half continued taking VYKAT XR.



IMPORTANT SAFETY INFORMATION (CONT'D)

VYKAT XR may cause serious side effects, including high blood sugar levels (hyperglycemia) (cont'd)

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

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How was hyperphagia measured?

Hyperphagia was measured by the Hyperphagia Questionnaire for Clinical Trials (HQ-CT), which asked caregivers about the individual's behavior seen in the previous 2 weeks

The lower the total score, the less hyperphagia.



What the hyperphagia questionnaire asked about:

- **Bargaining and manipulating for food** or repeatedly asking after being told “no”
- **Mood when denied food** or asked to stop talking about food
- **Sneaking food, stealing food, foraging through trash for food,** or waking up at night to look for food
- **Daily activities being interrupted** by food-related behaviors and time spent asking or talking about food

HQ-CT owned by FPWR. Contact information and permission to use: Foundation for Prader-Willi Research, www.fpwr.org

IMPORTANT SAFETY INFORMATION (CONT'D)

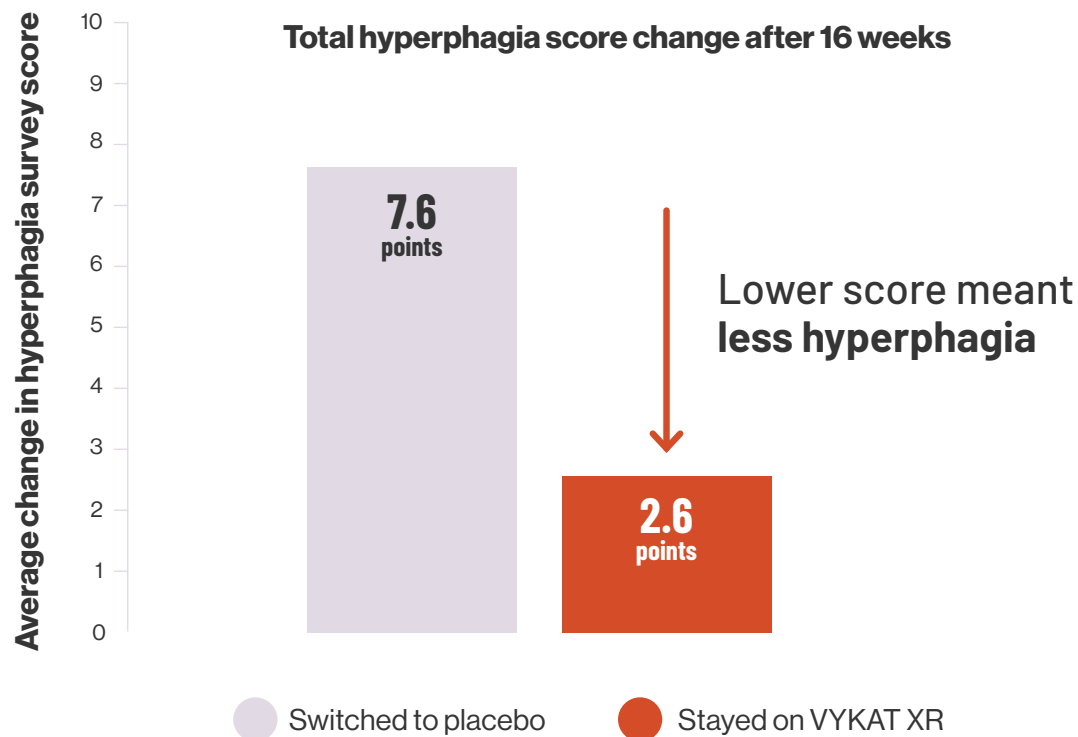
VYKAT XR may cause serious side effects, including (cont'd):

- **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.

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People taking VYKAT XR had less hyperphagia compared to placebo

In a 16-week study, people who switched to placebo had worse hyperphagia than those who continued taking VYKAT XR



Lessening hyperphagia can take time, so it's important to stick to a plan with VYKAT XR and your existing routines

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

VYKAT XR was well tolerated; less than 5% of people stopped taking treatment due to side effects

More than 5% of people taking VYKAT XR and 2% of people taking placebo in the clinical trial from Study 1 experienced the side effects below

Side effects	VYKAT XR 84 participants N (%)	Placebo 42 participants N (%)
Increased hair growth all over the body	36%	14%
Swelling in the body*	27%	12%
High blood sugar levels†	17%	5%
Rash‡	12%	2%
Fever	6%	0%
Joint pain	5%	2%
Flu	5%	2%
Cold	5%	2%

*Swelling/too much fluid can include the following areas of the body: hands, legs, feet, face, eyes, and lungs.

†Increased blood sugar levels include type 2 diabetes.

‡Rash includes those caused by direct contact with a substance or allergic reaction to one, those triggered by infections or autoimmune disorders, side effects from prescribed medicine, or reactions to certain foods.

IMPORTANT SAFETY INFORMATION (CONT'D)

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

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

It's important to take steps to work with your doctor during your treatment experience with VYKAT XR

You can:

- **Request guidance for monitoring side effects** like swelling and increased blood sugar from your doctor
- Tell your doctor about side effects **when they occur**
- **Make sure to request scheduled, routine follow-up visits** to assess your overall treatment journey

By taking these steps, you and your care team can address potential issues quickly

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

Layne

Huge football fan taking VYKAT XR


vykat[™] XR
(diazoxide choline) extended-release tablets

How to take VYKAT XR



VYKAT XR is taken once daily

Tablets are taken by mouth.



It can be taken with or without food

Tablets must be stored in their original packaging and be taken whole. Do not chew, crush, or break.



Doses are based on weight

When starting VYKAT XR, your doctor will tell you how much to take and when.

Everyone is different, so your doctor will work with you to find the appropriate dose for you

There are multiple dosage strengths and combinations of tablets you may need to take, and your doses may increase until you reach the dose that you will remain on until your doctor tells you otherwise.

It is important to take VYKAT XR exactly as your doctor prescribes

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

VYKAT XR works best when you don't forget a dose

Routines and consistent schedules may already be important tools you use to manage PWS

Here are some other helpful tips for remembering to take VYKAT XR:



As the dose of VYKAT XR may change, **write down any changes to your dose to stay up to date.**



Put a sticky note some place you will see it daily, like on your fridge or bathroom mirror.



Consider taking VYKAT XR with an activity you do every day. Some examples could be during a meal, when brushing your teeth, or something else that you do every day of the week.



Record each dose in a calendar to stay on track with VYKAT XR.



Set a daily alarm on your phone to help you remember your medication on busy days.



Download a medication reminder app on your phone to get alerts.

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

Food security, diet, and physical activity are still important when taking VYKAT XR

Even though it may be difficult, food security can help save a life

Food security starts by keeping food out of sight, but it doesn't end there.

It can also mean:



Setting scheduled times and expectations for snacks and meals.



Communicating any changes about when meals or snacks will happen.



Planning and discussing outings where there could be food or snacks.

All types of food security can lessen anxiety and help your loved one focus on other daily activities

IMPORTANT SAFETY INFORMATION (CONT'D)

Before taking VYKAT XR, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

- 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

Please see additional Important Safety Information throughout and full [Prescribing Information](#), including [Medication Guide](#), for VYKAT XR.

Diet and exercise are important for people living with PWS because of their low muscle mass and rate of metabolism

VYKAT XR can be added to your existing diet and exercise plan to better help with managing hyperphagia

Talk to a doctor who can help provide specific guidance designed for you.

IMPORTANT SAFETY INFORMATION (CONT'D)

Before taking VYKAT XR, tell your healthcare provider about all of your medical conditions, including if you (cont'd):

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.

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Ben

Ultimate fetch partner taking VYKAT XR


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You are not alone in your journey with PWS

Patient and Community Educators (PACE) are here to help support you before starting treatment



PACE
Patient & Community Educators

What are Patient and Community Educators?

Patient and Community Educators are a team of experts who offer non-medical support to patients and their caregivers.

They can help explain how VYKAT XR is taken, connect you with support resources, and answer general questions about what to expect during treatment.



Learn more about PACE

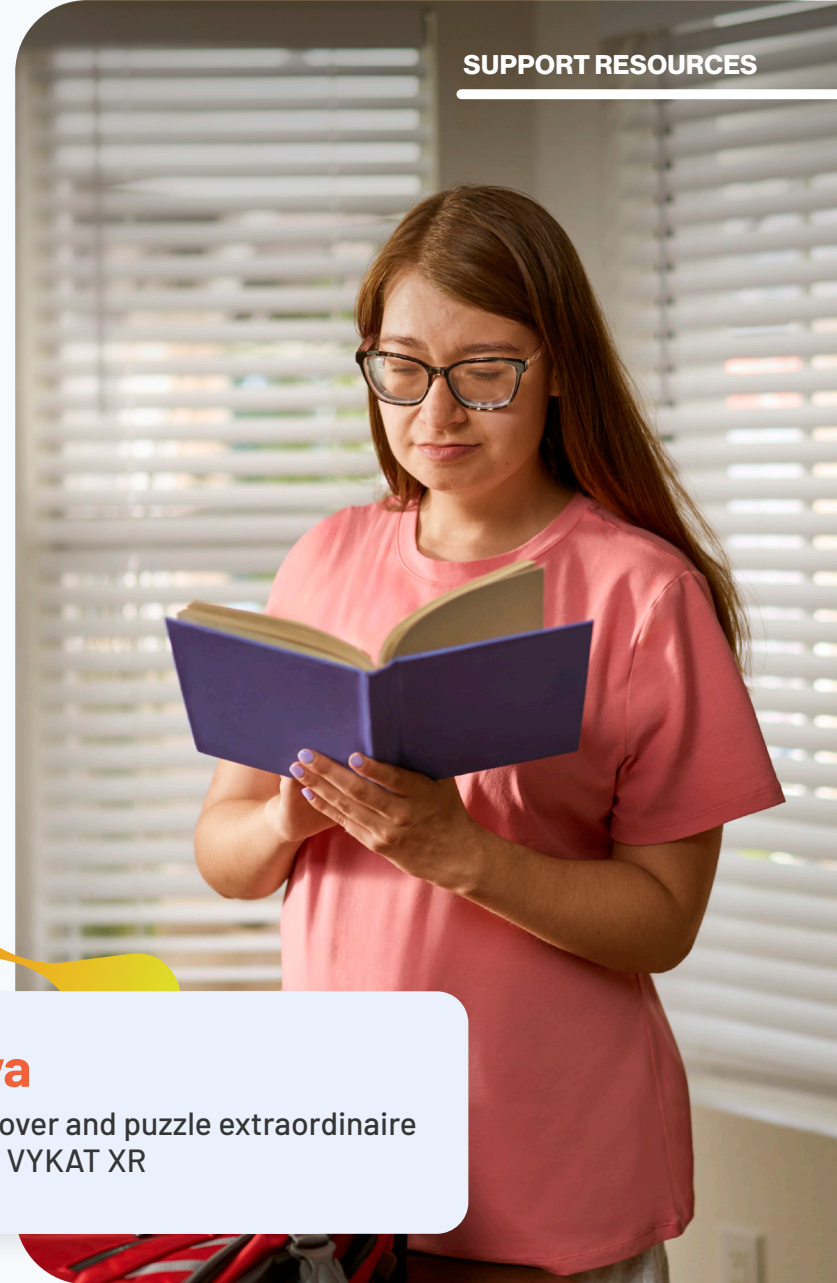
IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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Maya

Book lover and puzzle extraordinaire taking VYKAT XR

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The PACE team's goal is to make it easier for you to start and stay on VYKAT XR



After connecting with the PACE team, you can expect:

- A welcome call within 24-48 hours
- Education on VYKAT XR
- Information on support programs, events, and more

Patient and Community Educators are trained educators and registered nurses who provide non-medical, educational support. They do not provide medical advice, and all treatment decisions should be made with your healthcare provider.

**Connect with the PACE team at
1-833-SOLENO-1 (1-833-765-3661)**

Your PACE team member

When you're ready to meet with your PACE team member, fill in their information below to keep it handy.

Name:

Email:

Phone Number:

Notes:

IMPORTANT SAFETY INFORMATION (CONT'D)

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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(diazoxide choline) extended-release tablets

Ask your doctor about Soleno One™

After you have been prescribed VYKAT XR, get started with step-by-step support from Soleno One™

At the center of your support

Soleno One™ brings together expertise, education, and resources to streamline starting and staying on VYKAT XR. One-on-one support is just a phone call away if you have insurance questions, are moving, or need information or reminders about refills.

We're here to help Monday through Friday 8 AM-8 PM ET.
Call 1-833-SOLENO-1 (1-833-765-3661)



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Support communities and resources are available for people with PWS and their caregivers



Foundation for Prader-Willi Research

FPWR.org



Prader-Willi Syndrome Association | USA

PWSAUSA.org



International Prader-Willi Syndrome Organisation

IPWSO.org

IMPORTANT SAFETY INFORMATION (CONT'D)

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Ask your doctor about less hyperphagia with VYKAT XR

- People taking VYKAT XR had less hyperphagia compared to placebo
- VYKAT XR is taken once a day by mouth
- Soleno One[™] is available to support you or your loved one taking VYKAT XR



Stay up to date with the
latest resources and
information about VYKAT XR.
Sign up at VYKATXR.com

IMPORTANT SAFETY INFORMATION (CONT'D)

VYKAT XR may cause serious side effects, including high blood sugar levels (hyperglycemia) (cont'd)

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