


vykat™ XR
(diazoxide choline) extended-release tablets

What you need to know about VYKAT XR

The first and only FDA-approved treatment for hyperphagia in Prader-Willi syndrome (PWS).

Hyperphagia is known as extreme hunger, constant thoughts about food, and a constant urge to eat that cannot be satisfied with food.



VYKAT XR, also known as DCCR in clinical studies, is a prescription medicine taken by mouth for the treatment of hyperphagia in adults and children 4 years of age and older living with PWS.

SELECT 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).

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

About hyperphagia and VYKAT XR

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

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



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



It is possible to have hyperphagia and not be obese or even overweight.

People who stayed on VYKAT XR reported lower average hyperphagia scores compared to those who switched to placebo

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.

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.

Half of the people in the clinical trial were randomly selected to stop taking VYKAT XR after 2.5 to 4.5 years of treatment and take placebo (a sugar pill). The other half continued taking VYKAT XR.

People who switched to placebo had worse hyperphagia than those who continued taking VYKAT XR.

SELECT IMPORTANT SAFETY INFORMATION

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.

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


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Side effects, dosing, and support

VYKAT XR may cause serious side effects

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. Your doctor will check your blood sugar levels before and during treatment with VYKAT XR.

Too much fluid in your body (fluid overload):

Swelling in the body (edema) 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.

The most common side effects of VYKAT XR also include increased hair growth all over the body and rash. These are not all the possible side effects of VYKAT XR. Talk to your doctor for more information about side effects.

VYKAT XR tablets are taken once daily by mouth



When starting VYKAT XR, your doctor will tell you how much to take and when, so it's important to take VYKAT XR exactly as your doctor prescribes.

You are not alone in your journey with PWS

At the center of your support

After you have been prescribed 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. Soleno One™ brings together expertise, education, and resources to streamline starting and staying on VYKAT XR.



We're here to help Monday through Friday 8 AM-8 PM ET.
Call 1-833-SOLENO1 (1-833-765-3661)

Additional resources can help support you or your loved one with PWS



PWSAUSA.org



FPWR.org



IPWSO.org

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



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.
 - 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.

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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
- 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 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.

