

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.

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.