

MEDICATION GUIDE
VYKAT™ XR (vye kat ex ar)
(diazoxide choline)
extended-release tablets, for oral use

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, at least 1 time every week for the first 2 weeks of treatment, then at least 1 time every 4 weeks and as needed during treatment.
- check your blood sugar more often during the first few weeks of treatment if you have an increased chance of getting hyperglycemia.
- check your HbA1c, which is another measurement of blood sugar control, before starting treatment, then 1 time every 3 months and as needed during treatment.

If you get hyperglycemia during treatment with VYKAT XR, your healthcare provider may:

- give you medicines to treat hyperglycemia or change your dose if you already take them
- change your dose, temporarily stop, or permanently stop VYKAT XR

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

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| <ul style="list-style-type: none">○ hyperglycemia<ul style="list-style-type: none">▪ feel very thirsty▪ need to urinate more often than usual▪ have higher amounts of urine than usual▪ feel more hungry than usual▪ weight loss | <ul style="list-style-type: none">○ diabetic ketoacidosis<ul style="list-style-type: none">▪ nausea▪ vomiting▪ stomach-area (abdominal) pain▪ feel weak or very tired▪ trouble breathing |
|---|---|
- **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. 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.

What is VYKAT XR?

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). It is not known if VYKAT XR is safe and effective in children under 4 years of age.

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. See the end of this Medication Guide for a complete list of ingredients in VYKAT XR.

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
- 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. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Especially tell your healthcare provider if you take:

- medicines to lower blood sugar
- growth hormones
- corticosteroids
- diuretics (water pills)
- phenytoin
- warfarin

How should I take VYKAT XR?

- Take VYKAT XR exactly as your healthcare provider tells you to take it. Your healthcare provider will decide how much VYKAT XR you will take and may slowly increase your dose when you first start taking VYKAT XR.
- Take VYKAT XR by mouth 1 time per day with or without food.
- Swallow VYKAT XR tablets whole. **Do not** split, crush, or chew the tablets.
- You should not miss a dose of VYKAT XR. If you miss a dose of VYKAT XR, take the missed dose as soon as you remember. Do not take 2 doses of VYKAT XR at the same time to make up for a missed dose. If you missed a dose of VYKAT XR and did not remember to take another dose, call your healthcare provider to discuss what you should do next.
- **The dose of VYKAT XR is not the same as diazoxide oral suspension. Do not change** between VYKAT XR and diazoxide oral suspension products.

If you take too much VYKAT XR, call your healthcare provider or Poison Help Line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

What are the possible side effects of VYKAT XR?

- **See “What is the most important information I should know about VYKAT XR?”**

The most common side effects of VYKAT XR also include:

- increased hair growth all over the body
- 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 FDA at 1-800-FDA-1088.

How should I store VYKAT XR?

- Store VYKAT XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Close the bottle tightly after each dose.
- Keep VYKAT XR tablets dry (protect from humidity).
- The bottle contains a desiccant to help keep the tablets dry. Keep the desiccant in the VYKAT XR bottle.

Keep VYKAT XR and all medicines out of the reach of children.

General information about the safe and effective use of VYKAT XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use VYKAT XR for a condition for which it was not prescribed. Do not give VYKAT XR to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VYKAT XR that is written for health professionals.

What are the ingredients in VYKAT XR?

Active ingredient: diazoxide choline

Inactive ingredients: carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose magnesium stearate, polyethylene oxide, silicified microcrystalline cellulose, talc, titanium dioxide, and triacetin.

Manufactured for: Soleno Therapeutics, Inc., 100 Marine Parkway, Suite 400, Redwood City, CA 94065

For more information, call 1-833-765-3661.