

# Medication Guide

## KORLYM® (KOR-Lim) (mifepristone) tablets

### What is the most important information I should know about KORLYM?

#### KORLYM can cause serious side effects, including:

- **Loss of a pregnancy.** Women who can become pregnant must:
  - have a negative pregnancy test before starting KORLYM
  - have a negative pregnancy test before restarting KORLYM if you stop taking it for more than 14 days
  - use a non-hormonal form of birth control while taking KORLYM and for 1 month after stopping KORLYM. Talk to your doctor about how to prevent pregnancy. Tell your doctor right away if you think you may be pregnant.

### What is KORLYM?

KORLYM is a prescription medicine used to treat high blood sugar (hyperglycemia) caused by high cortisol levels in the blood (hypercortisolism) in adults with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or cannot have surgery.

KORLYM is not for people who have type 2 diabetes mellitus not caused by Cushing's syndrome. It is not known if KORLYM is safe and effective in children.

### Do not take KORLYM if you:

- **are pregnant.** See "What is the most important information I should know about KORLYM?"
- **are taking:**
  - simvastatin (Zocor®, Vytorin®, Simcor®)
  - lovastatin (Mevacor®, Altoprev®, Advicor®)
  - cyclosporine (Gengraf®, Neoral®, Restasis®, Sandimmune®)
  - dihydroergotamine (Migranal®)
  - ergotamine (Ergomar®, Migergot®)
  - fentanyl (Abstral®, Actiq®, Duragesic®, Fentora®, Lazanda®, Onsolis®, Sublimaze Preservative Free®, Subsys®)
  - pimozone (Orap®)
  - quinidine (Nuedexta®)
  - sirolimus (Rapamune®, Torisel®)
  - tacrolimus (Prograf®, Protopic®)
- must take corticosteroid medicines for other serious medical problems
- are a woman who still has her uterus (womb) **and** have:
  - unexplained bleeding from your vagina
  - changes in the cells lining your uterus (endometrial hyperplasia) or cancer of the lining of your uterus (endometrial cancer)
- are allergic to mifepristone or any of the ingredients in KORLYM. See the end of this Medication Guide for a complete list of ingredients in KORLYM.

Talk to your doctor before taking KORLYM if you have any of these conditions.

### What should I tell my doctor before taking KORLYM?

Before taking KORLYM, tell your doctor if you:

- are pregnant or plan to become pregnant
- have low potassium in your blood (hypokalemia)
- have or have had a bleeding problem or are taking medicines to thin your blood
- have or have had heart problems
- have had an organ transplant
- have been taking medicines called corticosteroids (cortisone, dexamethasone, methylprednisolone, prednisolone, prednisone)
- are breastfeeding or plan to breastfeed.

**Tell your doctor about all of the medicines you take**, including prescription and nonprescription medicines, vitamins and herbal supplements.

Using **KORLYM** with certain other medicines can affect each other. Using KORLYM with other medicines can cause serious side effects.

Especially tell your doctor if you take:

- medicines to treat:
  - fungal infections (such as ketoconazole)
  - depression
  - HIV infection
  - Hepatitis C infection
  - certain bacterial infections
  - high blood pressure
- steroid medicines such as prednisone
- thyroid hormones

Ask your doctor or pharmacist for a list of these medicines if you are not sure. Know the medicines you take. Keep a list of them to show to your doctor and pharmacist.

**How should I take KORLYM?**

- Take KORLYM exactly as your doctor tells you.
- Your doctor may change your dose if needed.
- KORLYM is usually taken 1 time each day.
- Take KORLYM with food.
- Swallow KORLYM whole. **Do not** split, crush or chew KORLYM tablets. If you cannot swallow KORLYM tablets whole, tell your doctor.

**What should I avoid while taking KORLYM?**

You should not drink grapefruit juice while you take KORLYM. Grapefruit juice may increase the amount of KORLYM in your blood and increase your chance of having side effects.

**What are the possible side effects of KORLYM?****KORLYM can cause serious side effects including:**

- **See “What is the most important information I should know about KORLYM?”**
- **loss of pregnancy**
- **reduced effects of adrenal hormones (adrenal insufficiency).** KORLYM stops an adrenal hormone in your body called cortisol from working. Tell your doctor right away if you have any symptoms of adrenal insufficiency. Symptoms may include:
  - unusual tiredness or weakness
  - nausea
  - fatigue
  - low blood pressure (hypotension)
  - low blood sugar (hypoglycemia)
- **low blood potassium (hypokalemia).** Your doctor should check the level of potassium in your blood before you start taking KORLYM and while you take it. Tell your doctor if you have any signs of low potassium. Signs may include:
  - muscle weakness, aches, or cramps
  - abnormal or irregular heartbeats (palpitations)
- **bleeding from the vagina.** KORLYM may cause the lining of your uterus to become thick and may cause your uterus to bleed. Tell your doctor right away about any bleeding from your vagina that is not normal for you.
- **disruption of menstrual cycle**
- **problems with the electrical system of your heart (QT interval prolongation).**
- **worsening of symptoms of other medical problems that are treated with corticosteroids when you take corticosteroids and KORLYM at the same time.**

The most common side effects of **KORLYM** include:

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| <ul style="list-style-type: none"><li>• nausea</li><li>• headache</li><li>• pain in your arms and legs (arthralgia)</li><li>• swelling of your arms and legs (peripheral edema)</li><li>• dizziness</li><li>• thickening of the lining of the uterus (endometrial hypertrophy)</li></ul> | <ul style="list-style-type: none"><li>• fatigue</li><li>• low potassium in your blood</li><li>• vomiting</li><li>• high blood pressure</li><li>• decreased appetite</li></ul> |
|--|---|

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of KORLYM.

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 KORLYM?**

Store KORLYM at room temperature, between 68°F to 77°F (20°C to 25°C).

**Keep KORLYM and all medicines out of the reach of children.**

**General information about the safe and effective use of KORLYM**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

Do not use KORLYM for a condition for which it was not prescribed. Do not give KORLYM to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about KORLYM that is written for healthcare professionals.

**What are the ingredients in KORLYM?**

**Active ingredient:** mifepristone

**Inactive ingredients:** silicified microcrystalline cellulose, sodium starch glycolate, hydroxypropylcellulose, sodium lauryl sulfate, magnesium stearate, hypromellose, titanium dioxide, triacetin, D&C yellow 10 aluminum lake, polysorbate 80, and FD&C yellow 6 aluminum lake.

Manufactured for: Corcept Therapeutics Incorporated, Menlo Park, CA 94025

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For more information, go to [www.korlym.com](http://www.korlym.com) or [www.corcept.com](http://www.corcept.com) or call 1-855-456-7596.