

A Patient Guide

Starting Treatment With Korlym® (mifepristone) 300 mg Tablets

INDICATIONS AND USAGE

Korlym® (mifepristone) is a cortisol receptor blocker indicated to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery.

Important Limitations of Use

Do not use for the treatment of type 2 diabetes mellitus unrelated to endogenous Cushing's syndrome.

IMPORTANT SAFETY INFORMATION

WARNING: TERMINATION OF PREGNANCY

Mifepristone has potent antiprogestational effects and will result in the termination of pregnancy. Pregnancy must therefore be excluded before the initiation of treatment with Korlym, or if treatment is interrupted for more than 14 days in females of reproductive potential.

Please be sure to read the Medication Guide starting on page 5.
Please see accompanying full Prescribing Information.



Korlym®
mifepristone
300 mg Tablets

All About Korlym

This brochure includes the Medication Guide for Korlym, the only oral medication approved to reduce elevated blood glucose (sugar) caused by high cortisol levels in patients with Cushing's syndrome. It is important that you read this information fully to help you use the medication safely.

To help you start and stay on Korlym, you'll enroll in SPARK, the Support Program for Access and Reimbursement for Korlym. See page 3 to learn more.

**Please be sure to read the Medication Guide starting on page 5.
Please see accompanying full Prescribing Information.**

All About SPARK

Getting Started With SPARK

The SPARK Contact Center will coordinate the services you need to start and stay on treatment with Korlym.

Coverage and Reimbursement

SPARK will work with your insurance company to verify coverage and reimbursement benefits and provide you with a full explanation of those benefits. In addition, SPARK will verify your eligibility for copay assistance and, if needed, research alternate coverage options if you cannot afford Korlym.

Patient Assistance Programs

Your SPARK reimbursement specialist will review your eligibility for financial assistance programs if you cannot afford care. This includes support for eligible uninsured patients through the Korlym Patient Assistance Program and referrals to independent nonprofit organizations.

Korlym Deliveries

SPARK will send your written prescription to a specialty pharmacy. The approved specialty pharmacy for Korlym is Dohmen Life Science Services.

Dohmen Life Science Services will contact you directly and arrange to have Korlym shipped to your home. They will also reach out to you and your doctor when your prescription needs to be refilled.

Additionally, Dohmen Life Science Services will contact you each month to verify your address and the expected delivery date for Korlym.

Ongoing Support

Our dedicated SPARK reimbursement specialists are available to assist you Monday through Friday, 8 AM to 7 PM Eastern time, at 1-855-4KORLYM (1-855-456-7596).

You can also visit www.korlym.com for more information.



Getting Started With SPARK (continued)

To begin, you and your doctor should review the Medication Guide together to help you understand the risks and benefits of Korlym treatment, including the risk of pregnancy termination, low potassium levels, adrenal insufficiency, and drug interactions.

After reviewing the information, your doctor will help you fill out the Patient Enrollment and Consent Form. After you and your doctor have completed the form, your doctor will send it to the SPARK Contact Center.



Review the Medication Guide and the risks of Korlym treatment with your doctor.



Complete and sign the enrollment form with your doctor. Both you and your doctor must sign the form. Women who could become pregnant must have a negative pregnancy blood test before registering and receiving treatment.



Your doctor will send the form to the SPARK Contact Center.

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Korlym Medication Guide

Korlym® (KOR-lim) (mifepristone) tablets

Read this Medication Guide before you start taking Korlym and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

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.



Korlym Medication Guide (continued)

Who should not take Korlym?

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®, Juvisync®, 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 (Neudexta®)
 - 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.

**Please be sure to read the Medication Guide starting on page 5.
Please see accompanying full Prescribing Information.**

What should I tell my doctor before taking Korlym?

Before taking Korlym, tell your doctor if you:

- 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. Korlym passes into your breast milk and may harm your baby. You and your doctor should decide if you will take Korlym or breastfeed. You should not do both.

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
- 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.



Korlym Medication Guide (continued)

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?"**
- **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)

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- **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.
- **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:

- nausea
- fatigue
- headache
- low potassium in your blood
- pain in your arms and legs (arthralgia)
- vomiting
- swelling of your arms and legs (peripheral edema)
- high blood pressure
- dizziness
- decreased appetite
- thickening of the lining of the uterus (endometrial hypertrophy)

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. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.



Korlym Medication Guide (continued)

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.

This Medication Guide summarizes the most important information about Korlym. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Korlym that is written for healthcare professionals.

For more information, call 1-855-4KORLYM (1-855-456-7596) or visit www.korlym.com or www.corcept.com.

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.

This Medication Guide has been approved by the US Food and Drug Administration.

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Important Safety Information

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IMPORTANT SAFETY INFORMATION

WARNING: TERMINATION OF PREGNANCY

Mifepristone is a potent antagonist of progesterone and cortisol via the progesterone and glucocorticoid (GR-II) receptors, respectively. The antiprogestational effects will result in the termination of pregnancy. Pregnancy must therefore be excluded before the initiation of treatment with Korlym and prevented during treatment and for one month after stopping treatment by the use of a non-hormonal medically acceptable method of contraception unless the patient has had a surgical sterilization, in which case no additional contraception is needed. Pregnancy must also be excluded if treatment is interrupted for more than 14 days in females of reproductive potential.

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