
STARTING ON KORLYM[®]

An informational resource to
help guide you as you begin treatment



How to
Take Korlym



What to
Expect



Importance of
Monitoring

INDICATION

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.

IMPORTANT SAFETY INFORMATION

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** or 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 one 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.

Please see additional Important Safety Information throughout, and [Important Facts](#) about Korlym.

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WHAT IS CUSHING SYNDROME (HYPERCORTISOLISM)?

Cushing syndrome (hypercortisolism) is a serious condition that occurs when your body has excess cortisol. There are different causes of hypercortisolism, but before we go over what they are, it's important to understand what cortisol is.

What Is Cortisol?

Cortisol is a natural hormone that your body makes to regulate several functions, including:



Blood sugar levels



Metabolism



Blood pressure



Salt and water balance



Mood and memory



Immune system



Stress

Cortisol can also act as an anti-inflammatory.

Why Is Excess Cortisol Harmful to Your Body?

Your body has a natural rhythm when it comes to making cortisol.



More in the morning



Less at night

Hypercortisolism disrupts that rhythm and overproduces cortisol. This excess cortisol can lead to a variety of symptoms, like:

- Extreme fatigue
- Abdominal weight gain
- Skin changes

Visit [Korlym.com](https://www.korlym.com) for a detailed list of symptoms.

IMPORTANT SAFETY INFORMATION (CONT.)

Do not take Korlym if you:

- are pregnant
- are taking medicines that contain simvastatin, lovastatin, cyclosporine, dihydroergotamine, ergotamine, fentanyl, pimozide, quinidine, sirolimus, or tacrolimus
- must take corticosteroid medicines for other serious medical problems
- have experienced unexplained vaginal bleeding, 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**.

Please see additional Important Safety Information throughout, and [Important Facts](#) about Korlym.

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mifepristone
300 mg Tablets

WHAT IS CUSHING SYNDROME (HYPERCORTISOLISM)? (CONT.)

Cushing syndrome is caused by excess cortisol—also called hypercortisolism.

Exogenous Cushing syndrome

is when excess cortisol is caused by something outside your body, like steroid medications.

Endogenous Cushing syndrome

is when something inside your body causes it to overproduce cortisol.

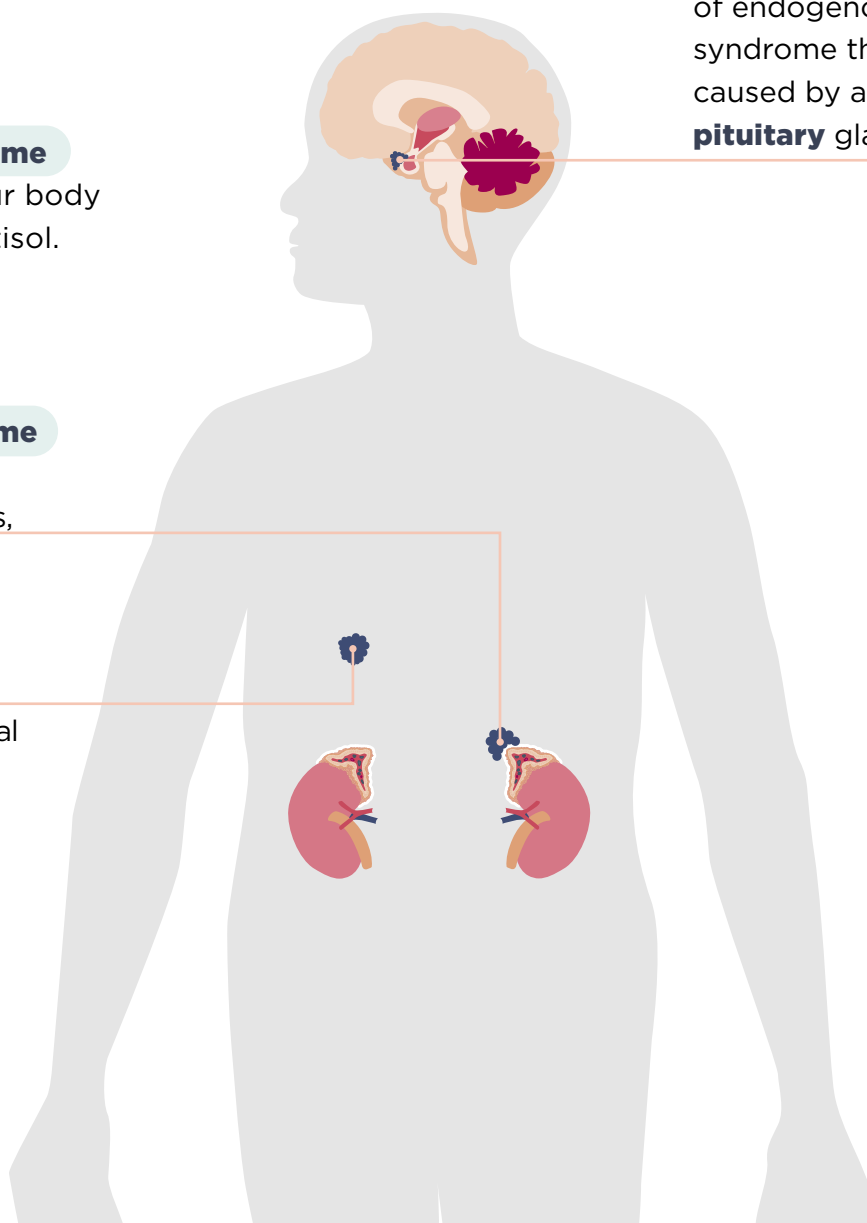
Cushing disease is a form of endogenous Cushing syndrome that may be caused by a growth on the **pituitary** gland.

The cause of

endogenous Cushing syndrome

may be a growth on the **pituitary** gland, **adrenal** glands, or somewhere else in the body. If the growth is located somewhere else, it's called an **ectopic** source.

These growths cause the adrenal glands to overproduce cortisol.



IMPORTANT SAFETY INFORMATION (CONT.)

What Are the Possible Side Effects of Korlym?

Serious side effects of Korlym may also include:

- **reduced effects of adrenal hormones (adrenal insufficiency).** Tell your doctor right away if you have unusual tiredness or weakness, nausea, fatigue, low blood pressure (hypotension), low blood sugar (hypoglycemia)

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WHAT IS KORLYM AND WHY IS IT BEING PRESCRIBED?

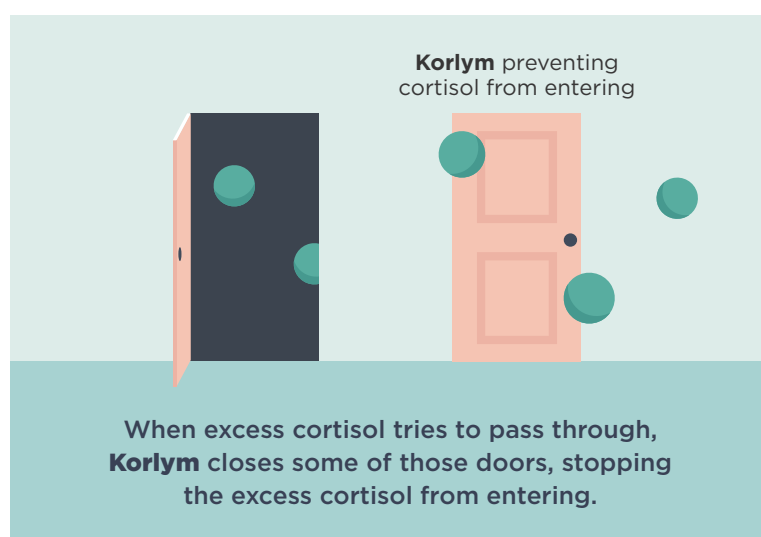
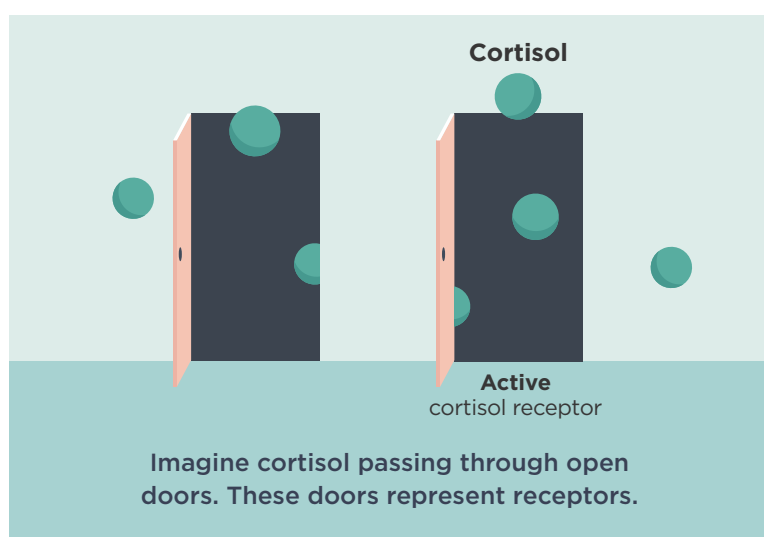
Korlym is a daily oral treatment that has been shown to reduce certain negative effects of excess cortisol activity.

Cortisol impacts different parts of your body by attaching to receptors, which are located in almost every cell.

People with hypercortisolism overproduce cortisol, which means more receptors are activated than necessary. This can lead to multiple symptoms throughout your body.

How Does Korlym Work?

The goal of Korlym is to improve certain symptoms caused by excess cortisol. To do this, **Korlym** competes with cortisol by attaching to some receptors so excess cortisol cannot.



Korlym does not stop your body from making cortisol, so you may still have high cortisol levels throughout treatment. If necessary, the effects of **Korlym** are reversible.

The best way to know if Korlym is working is to see if your symptoms have improved.

Be sure to keep track of your symptoms to review with your healthcare professional. You can record these using the tracking pages in the **Korlym** Patient Binder.

IMPORTANT SAFETY INFORMATION (CONT.)

What Are the Possible Side Effects of Korlym?

Serious side effects of Korlym may also include (cont.):

- **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 muscle weakness, aches or cramps, abnormal or irregular heartbeats (palpitations)

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GETTING STARTED ON KORLYM

Before starting **Korlym** and throughout treatment, you and your healthcare professional will routinely check your:

- Blood sugar
- Blood pressure
- Potassium levels

How to Take Korlym

Take **Korlym** exactly as prescribed by your healthcare professional.



Once a day



With a meal



Swallow whole



Do not split, crush, or chew

Treatment starts with one 300-mg tablet daily.

300
MG/DAY



1 tablet

600
MG/DAY



2 tablets

900
MG/DAY



3 tablets

1200
MG/DAY



4 tablets
Maximum dose

Over time, your healthcare professional may slowly increase your dose—1 tablet at a time—to up to 4 tablets, or 1200 mg daily. This will depend on how your body responds to treatment and how your symptoms improve. Your dose will likely not change more often than every 2-4 weeks.

In people with reduced kidney function or those with mild-to-moderate liver problems, the maximum dose of **Korlym** should be limited to 600 mg/day. Talk to your healthcare professional if you have a history of kidney or liver problems.

IMPORTANT SAFETY INFORMATION (CONT.)

What Are the Possible Side Effects of Korlym?

Serious side effects of **Korlym** may also include (cont.):

- **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**

Please see additional Important Safety Information throughout, and [Important Facts](#) about **Korlym**.

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IMPORTANT MONITORING DURING TREATMENT

Before starting **Korlym** and throughout treatment, you and your healthcare professional will routinely check your:



Blood sugar



Blood pressure



Potassium levels

You can check your blood sugar and blood pressure at home. You will need to get blood work done to check your potassium levels and your healthcare professional will review the results with you.



Monitoring Blood Sugar

Changes in your blood sugar are an early and ongoing way to see how your treatment with **Korlym** is working. Tell your healthcare professional if you feel:

- Tired
- Shaky
- Anxious
- Irritable
- Very hungry

Also tell your healthcare professional if you have low blood sugar levels, or if you've noticed changes to your heartbeat, skin color, or sweat.



Monitoring Blood Pressure

You should routinely check your blood pressure, but especially if you feel:

- Dizzy
- Faint
- Nauseous
- Tired

Tell your healthcare professional if you:

- Fainted
- Had changes to your vision
- Struggle to concentrate
- Had changes in blood pressure

IMPORTANT SAFETY INFORMATION (CONT.)

What Are the Possible Side Effects of Korlym?

Serious side effects of Korlym may also include (cont.):

- 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.

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IMPORTANT MONITORING DURING TREATMENT (CONT.)



Monitoring Potassium Levels

Low potassium levels (hypokalemia) may happen when taking **Korlym**. Low potassium can affect your heart rate and blood pressure. Routine checks can help your healthcare professional act quickly if your potassium levels drop.

Tell your healthcare professional if you experience:

- Muscle weakness, aches, or cramps
- Constipation
- Abnormal or irregular heartbeats (palpitations)
- Swelling of your hands or feet (edema)

You should have your potassium levels checked:

Before starting treatment

1-2 weeks after your first dose

1-2 weeks after a dose increase

Periodically throughout treatment

IMPORTANT SAFETY INFORMATION (CONT.)

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, and thickening of the lining of the uterus (endometrial hypertrophy).

These are not all the possible side effects of **Korlym**. Call your doctor for medical advice about side effects. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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WHAT TO EXPECT DURING TREATMENT

Your body may need some time to adjust once you begin taking **Korlym**. You may notice some improvements quickly, while others may take more time. Some side effects may be your body adjusting to **Korlym**, while others may possibly require adjustments in your other medications. Tell your healthcare professional right away about any side effects you experience. It may be helpful to tell your loved ones about **Korlym** so they can help support you during this time.

Clinical Trial Results

In the **Korlym** clinical trial, people taking **Korlym** saw:



Improved blood sugars



Less need for antidiabetic medicine (like insulin)



Weight loss*



Improved mood*

*In the clinical study, some patients receiving **Korlym** reported changes in weight, waist measurement, appearance (such as the clearing of acne), mood, symptoms of depression, ability to think clearly, and muscle strength. It is uncertain whether **Korlym** caused these changes. At the start of the trial, patients had an average weight of 220 pounds and an average waistline of 47 inches.

Potential Side Effects

The most common side effects 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)

Avoid grapefruit juice while you take **Korlym**, as it may increase the chance of side effects.

These are not all the possible side effects of **Korlym**. If you experience any side effects, tell your healthcare professional right away. Please see Important Safety Information on the next page.

Be sure to ask your healthcare professional how **Korlym** may interact with any of your other medications.

Or you can call **1-855-4KORLYM (1-855-456-7596)** to ask your **Specialty Pharmacist**.

IMPORTANT SAFETY INFORMATION (CONT.)

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.

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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.

You should not drink grapefruit juice while you take **Korlym**.

Tell your healthcare provider about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using **Korlym** with certain other medicines may affect each other or may cause serious side effects.

Please see [Important Facts](#) about Korlym with important warning.

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