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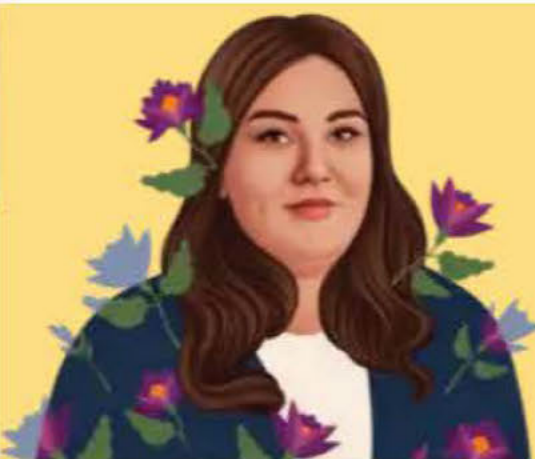
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What is Recorlev[®]?

INDICATION AND IMPORTANT SAFETY INFORMATION FOR Recorlev[®] (levoketoconazole) tablets



What is Recorlev?

- Recorlev is a prescription medicine used to treat high cortisol (endogenous hypercortisolemia) levels in adult patients with Cushing's syndrome who cannot have surgery or who have had surgery that did not cure their Cushing's syndrome.

What does it do?

Recorlev[®] (levoketoconazole) is a medicine taken by mouth that can help normalize your cortisol levels.

How does Recorlev work?

Recorlev blocks the key steps in the making of cortisol and testosterone in the body. This is important because the goal of managing Cushing's is to get your cortisol levels back to normal.

Recorlev has been studied in clinical trials for more than 3 years

In the LOGICS clinical study, Recorlev was proven to lower cortisol levels*

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Recorlev

More patients (52%) who were on a stable and steady dose of Recorlev had normal cortisol levels*

Placebo

(a medicine with no effect)

Patients who stopped taking Recorlev and started taking a placebo lost control of their cortisol levels* (6% had normal cortisol levels*)

The SONICS clinical study supported the efficacy and safety results from LOGICS

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31%

of patients had normal cortisol levels*
after taking Recorlev for 6 months
without changing their dose

67%

of patients who moved on to the second
part of the study had normal cortisol
levels* by the end of the study

The clinical study had a strict rule not to change patients' doses during those 6 months. This may not be your experience. Your doctor may change your dose of Recorlev during treatment, which is completely normal.

*Cortisol levels were measured with a urine test.

How to get Recorlev

Recorlev is only available with a doctor's prescription. PANTHERx Rare Pharmacy is the only pharmacy that carries Recorlev and will have it delivered right to you. Your support team will help make sure you receive your treatment.

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Talk to your doctor about starting Recorlev if you have symptoms of Cushing's or want to try a different medicine for Cushing's.

LEARN HOW TO MONITOR YOUR PROGRESS >

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Do not take Recorlev if you:

- have or have had liver problems.
- take certain other medicines that cause QT prolongation.
- have a history of certain heart problems which may include one of the following conditions: torsades de pointes, ventricular tachycardia, ventricular fibrillation, or long QT syndrome.
- are allergic to levoketoconazole, ketoconazole, or any of the ingredients in Recorlev, or take certain medicines that may affect how your liver works. If you are not sure if you take these medicines, ask your healthcare provider.

Before taking Recorlev, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had liver problems.
- have any heart problems, including a condition called long QT syndrome.
- have a history of low blood levels of potassium or magnesium.

- are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Recorlev and other medicines may affect each other causing side effects.

What is the most important information I should know about Recorlev?

Recorlev can cause serious side effects, including:

- **Liver damage (hepatotoxicity).** Hepatotoxicity can happen in people who take Recorlev. Some people who are treated with ketoconazole, a medicine like the active ingredient in Recorlev, had serious liver problems that required a liver transplant or led to death.

Call your healthcare provider right away if you have: pain on the upper right side of your stomach area associated with nausea, unusual fatigue, yellowing of your skin or the whites of your eyes, or unusual bruising or bleeding.

Recorlev should not be used if you have: cirrhosis, active or poorly controlled liver disease, frequent stones in your gallbladder, or history of liver problems due to use of a drug.

Your healthcare provider will do liver tests before and during treatment with Recorlev.

- **Heart rhythm problems (QT prolongation).** Recorlev can cause a heart problem called QT interval prolongation, or QT prolongation. QT prolongation can cause irregular heartbeats that can be life threatening.

Call your healthcare provider right away if you: feel severe lightheadedness or if you faint during treatment with Recorlev.

Low blood electrolyte levels of potassium and magnesium can increase your chances of QT prolongation during treatment with Recorlev.

Your healthcare provider will check your heart with a test called an electrocardiogram (ECG) and do blood tests to check your blood electrolyte levels before and during treatment with Recorlev.

Recorlev should not be taken with certain other medicines that cause QT prolongation. Talk to your healthcare provider about the medicines you are taking before you start taking Recorlev.

- **Low cortisol levels (adrenal insufficiency).** Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones, such as cortisol. Recorlev may cause adrenal function insufficiency by excessively lowering production of cortisol.

- **Call your healthcare provider right away if** you have one or more of the following symptoms, as these may be symptoms of reduced adrenal function: nausea or vomiting,

unusual fatigue, unexplained stomach pain, loss of appetite, body aches, dizziness, low blood pressure, abnormal electrolyte levels, or low blood sugar.

Your healthcare provider will collect blood or urine samples to measure your cortisol.

How should I take Recorlev?

- Take Recorlev exactly as your healthcare provider tells you. Your healthcare provider will tell you how much Recorlev to take and when to take it.
- If you miss a dose of Recorlev, take the next dose at your regular scheduled time.
- If you take too much Recorlev, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking Recorlev?

- Drinking alcohol to excess while taking Recorlev may increase your chances of having serious side effects.

What are the possible side effects of Recorlev?

Recorlev may cause serious side effects, including:

- **Hypersensitivity reactions.** Serious allergic reactions can happen in people who take Recorlev. Call your healthcare provider right away, or visit an emergency center, if you get a rash, itching, hives, fever, swelling of the lips or tongue, chest pain, or have trouble breathing. These could be signs of a serious allergic reaction.
- **Decreased testosterone.** Recorlev may lower testosterone levels in males (breast enlargement, erectile dysfunction) and females (low desire for sex and mood changes).

The most common side effects of Recorlev include nausea/vomiting, low potassium, easy bleeding/easy bruising, high blood pressure, headache, liver injury, abnormal uterine bleeding, redness of the skin, fatigue, upset stomach, arthritis, upper respiratory infection, muscle pain, abnormal heart rhythm, back pain, sleep disturbances, and fluid retention.

Recorlev may cause fertility problems, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of Recorlev.

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

For more information, please see the [Full Prescribing Information](#) and [Medication Guide](#), including **Boxed Warning, for Recorlev.**

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[One-on-one support](#) ▼



Taking Recorlev[®]

Recorlev is a prescription medicine taken by mouth twice a day with or without food



INDICATION AND IMPORTANT SAFETY INFORMATION FOR Recorlev[®] (levoketoconazole) tablets



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Twice a day

Taken with or without food



Personalized dosing

- Your doctor will personalize your dose to ensure you're taking the right amount for you
- Personalizing means your dose may change more than once while you're taking Recorlev[®] (levoketoconazole). This is normal. Your doctor is trying to find the right dose of Recorlev for you to manage your cortisol levels and side effects

**A clinical pharmacist
from PANTHERx Rare Pharmacy will
check in with you regularly to see how
you're feeling and answer any
questions you may have**

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Monitoring and side effects

Monitoring

As with other medicines for Cushing's, monitoring by your doctor is important so they know how you're doing



Measuring your cortisol during treatment with Recorlev helps your doctor tell if it is under control



Heart and liver tests before and during treatment with Recorlev will help your doctor avoid side effects



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Possible side effects

Side effects can occur with Recorlev, including some that are serious

While you're on Recorlev, your doctor will test you regularly.

Remember to tell your doctor or pharmacist how you're feeling while taking Recorlev so they can find the right dose for you.

It's important to share with your doctor what medicines you're taking, including vitamins and over-the-counter medicine.

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