



Getting started with RECORLEV[®] (levoketoconazole): Treatment tips and support guide

Indication

RECORLEV (levoketoconazole) is a prescription medicine used to treat high cortisol 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. RECORLEV is not to be used for treatment of fungal infections.

Important Safety Information

- **RECORLEV can cause serious side effects, including:**
 - **Liver damage (hepatotoxicity):** Some people who were 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 doctor 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

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including Boxed Warning, for RECORLEV.

The importance of getting your cortisol levels back to normal

Cortisol is a hormone that plays many important roles in the body such as **maintaining blood pressure** and **regulating blood sugar**.

However, when you have too much cortisol over a long period of time, it can have a harmful snowball effect on your entire body.

What is Cushing's syndrome?

There are two types of Cushing's syndrome, sometimes called hypercortisolemia.

Endogenous Cushing's syndrome occurs when your body makes too much cortisol over a long period of time.

Endogenous Cushing's syndrome is most commonly caused by:

- A tumor of the pituitary gland
- A tumor of the adrenal gland

The physical and emotional impact of Cushing's syndrome can be high. Common signs and symptoms include:



Weight gain



High blood sugar



High blood pressure



Depression and feeling irritable



Infection



Irregular periods



Poor concentration



Bone fragility



Cardiovascular disease



Fatigue

A main goal of treating Cushing's syndrome is to get your cortisol levels back to normal.

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What is RECORLEV®?¹-³

RECORLEV:

- Is a twice-daily pill proven to bring cortisol levels back to normal
- Is the first FDA-approved treatment for high cortisol 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
- Addresses the root problem of Cushing's syndrome (high cortisol) by blocking the key steps in making cortisol in the body
- Has a proven safety profile, with individualized dosing and monitoring rules based on the clinical studies



Your doctor will work with you to monitor your cortisol levels and help manage any symptoms and/or side effects you may experience.

Important Safety Information (Cont'd)

- **RECORLEV can cause serious side effects, including: (Cont'd)**
 - **Heart rhythm problems (QT prolongation): QT prolongation can cause irregular heartbeats that can be life-threatening**
 - Call your doctor right away if you feel severe lightheadedness or if you faint

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including Boxed Warning, for RECORLEV.

Recorlev®
(levoketoconazole)

Treatment tips as you begin RECORLEV®

It's important to:



- Take RECORLEV as prescribed by your doctor
- Talk to your doctor about how your treatment is going
- Be patient as your body adjusts to therapy

Your body may have become used to excess cortisol over a long period of time, even though it's harmful. As RECORLEV starts to lower cortisol levels, you may begin to experience **cortisol withdrawal**.

Flu-like symptoms that can occur in the first few weeks when taking a medicine that lowers cortisol levels include:



- Fatigue
- Nausea
- Vomiting
- Headache
- Muscle aches and pain

These feelings can be uncomfortable and may be a sign that RECORLEV is working, but could also be a sign of a more serious condition. Talk to your doctor about any symptoms you experience while taking RECORLEV.



You'll be able to contact your Patient Access Manager (PAM) any time via call, text, or email. Your PAM can be especially helpful during your first few weeks while adjusting to therapy.



Your PAM is there for you.
Don't hesitate to call!
Scan the QR code to learn more.

Important Safety Information (Cont'd)

- **RECORLEV can cause serious side effects, including: (Cont'd)**
 - Low cortisol levels (adrenal insufficiency): RECORLEV may cause adrenal insufficiency by excessively lowering production of cortisol
 - Call your doctor right away if you have nausea, vomiting, dizziness, unusual fatigue, low blood pressure, unexplained stomach pain, abnormal electrolyte levels, loss of appetite, low blood sugar, or body aches

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including **Boxed Warning, for RECORLEV.**

Monitoring your treatment

The recommended starting dose of RECORLEV[®] is 150 mg taken twice a day. Your doctor may increase or decrease your dose based on how you are feeling.



- If you have symptoms that are uncomfortable, speak to your doctor. Your dose may need to be brought down to help you feel better while taking RECORLEV
- If you're feeling okay but not seeing the results you want, your dose may be brought up



Your doctor will likely monitor your cortisol levels during your first month and throughout your therapy. Measuring cortisol levels is the best way of knowing the medication is working.

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Recorlev[®]
(levoketoconazole)

Possible side effects with RECORLEV®

RECORLEV can cause serious side effects such as liver damage (hepatotoxicity) and heart rhythm problems (QT interval prolongation)

Additional side effects can include:

- Low cortisol levels (adrenal insufficiency)
- Hypersensitivity reactions (allergic reactions)
- Decreased testosterone

Most common side effects 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.

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Hear from our Patient Ambassadors about RECORLEV[®]

Mark, 57, Massachusetts

"Having more control over my Cushing's symptoms has meant I can think less about my symptoms and more about living my life. It's been really positive for me to have stable, normal cortisol levels."



Emily, 36, California

"When I started RECORLEV, the side effects were challenging but once those subsided and my cortisol levels normalized, I have energy again to do the things that are important to me."

Important Safety Information (Cont'd)

- Do not take RECORLEV if you:
 - Have cirrhosis, active or poorly controlled liver disease, frequent stones in gallbladder, or history of liver problems due to use of a drug

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including Boxed Warning, for RECORLEV.


Recorlev[®]
(levoketoconazole)

Xeris CareConnection™ support is here



Xeris CareConnection™ offers a range of support services. Your team includes a dedicated PAM and PANTHERx Rare Pharmacy.



Your PAM will:

- Answer any questions or concerns you may have while taking RECORLEV®
- Connect you to a clinical pharmacist who specializes in endocrinology products and will check in with you to see how you are doing with treatment
- Connect you with patient advocacy organizations that offer resources and support for those living with Cushing's
- If you're not sure who your PAM is, contact patientaccess@xerispharma.com

\$0

Eligible patients may pay as little as \$0 for their prescription through the RECORLEV Co-pay Savings Program.

Eligibility requirements, restrictions and limitations apply.

Important Safety Information (Cont'd)

- Do not take RECORLEV if you: (Cont'd)
 - Take certain medicines that cause QT prolongation or may affect how your liver works, such as CYP3A4 inhibitors

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including Boxed Warning, for RECORLEV.



Getting your RECORLEV® prescription

PANTHERx Rare Pharmacy is the only specialty pharmacy through which you can get RECORLEV. Once your prescription is received, your PANTHERx Rare Pharmacy Case Manager will work with you and your doctor's office to confirm your insurance information and the address where you want your RECORLEV sent.



If you have questions or concerns, please call PANTHERx at **1-844-444-RCLV (7258)**. Be sure to answer calls from PANTHERx to schedule shipment of your medication.

Important Safety Information (Cont'd)

- Do not take RECORLEV if you: (Cont'd)
 - 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

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including Boxed Warning, for RECORLEV.



Tips for talking to your doctor

You are your best advocate when working with your doctor during your Cushing's treatment journey. Be sure to tell your doctor about how you're feeling during your treatment, including signs of progress and any side effects you may experience. Consider what support you would like to have from your doctor.

Be sure to describe your progress in detail.

Progress

- How has your progress been in reaching treatment goals?
- How have your symptoms of Cushing's syndrome changed?
- How would you like your doctor and PAM to support you on your journey?
- Have you noticed a change in your energy levels or clarity of thought?

The more information you can share with your doctor about how you're feeling, the more your doctor will be able to help you.



Your PAM can help you understand what to keep track of and how to navigate discussions with your doctor. Don't hesitate to call, text, or email your PAM!

PAM Contact Info

Name: _____

Phone: _____

Email: _____

PANTHERx: 1-844-444-RCLV (7258)

Important Safety Information (Cont'd)

- Do not take RECORLEV if you: (Cont'd)
 - Are allergic to levoketoconazole, ketoconazole, or any of the ingredients in RECORLEV

Please see additional Important Safety Information throughout and [full Prescribing Information](#), including **Boxed Warning, for RECORLEV.**



To sign up to receive more information, scan QR code or visit [RECORLEVConnect.com](https://www.RECORLEVConnect.com)

Important Safety Information (Cont'd)

- Serious allergic reactions can happen in people who take RECORLEV, including rash, itching, hives, fever, swelling of the lips or tongue, chest pain, or trouble breathing
- RECORLEV may lower testosterone levels. For males, symptoms include breast enlargement and erectile dysfunction. For females, symptoms include low desire for sex and mood changes
- The most common side effects of RECORLEV include nausea, vomiting, low potassium, easy bleeding or bruising, high blood pressure, headache, liver injury, abnormal uterine bleeding, redness of the skin, fatigue, abdominal pain or upset stomach, arthritis, upper respiratory infection, muscle pain, abnormal heart rhythm, back pain, sleep disturbances, and fluid retention
- Before taking RECORLEV, tell your doctor about your medical conditions, medicines you take, and if you are breast feeding or plan to. RECORLEV may cause fertility problems in females and males, which may affect ability to have children
- You are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088

Please see additional Important Safety Information throughout. For more information, see [Medication Guide](#) and [full Prescribing Information](#) at www.RECORLEV.com.

References: **1.** RECORLEV [prescribing information]. Chicago, IL: Xeris Pharmaceuticals, Inc. **2.** Pivonello R, Zacharieva S, Elenkova A, et al. Levoketoconazole in the treatment of patients with endogenous Cushing's syndrome: a double-blind, placebo-controlled, randomized withdrawal study (LOGICS). *Pituitary*. 2022;25(6):911-926. doi:10.1007/s11102-022-01263-7 **3.** Fleseriu M, Pivonello R, Elenkova A, et al. Efficacy and safety of levoketoconazole in the treatment of endogenous Cushing's syndrome (SONICS): a phase 3, multicentre, open-label, single-arm trial [published correction appears in *Lancet Diabetes Endocrinol*. 2019 Nov;7(11):e22. doi: 10.1016/S2213-8587(19)30322-5]. *Lancet Diabetes Endocrinol*. 2019;7(11):855-865. doi:10.1016/S2213-8587(19)30313-4



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