Recorlev®
(levoketoconazole)

# Getting your patients started

**Indication & Important Safety Information for Recorlev® (levoketoconazole)**

**BOXED WARNING: HEPATOTOXICITY AND QT PROLONGATION**

**HEPATOTOXICITY**

**Cases of hepatotoxicity with fatal outcome or requiring liver transplantation have been reported with oral ketoconazole. Some patients had no obvious risk factors for liver disease. Recorlev is associated with serious hepatotoxicity. Evaluate liver enzymes prior to and during treatment.**

**QT PROLONGATION**

**Recorlev is associated with dose-related QT interval prolongation. QT interval prolongation may result in life-threatening ventricular dysrhythmias such as torsades de pointes. Perform ECG and correct hypokalemia and hypomagnesemia prior to and during treatment.**

**INDICATION**

Recorlev is a cortisol synthesis inhibitor indicated for the treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative.

Limitations of Use

Recorlev is not approved for the treatment of fungal infections.

**Please see additional Important Safety Information throughout and Full Prescribing Information, including Boxed Warning.**

# Getting your patients started on Recorlev® (levoketoconazole) is simple

## Xeris CareConnection™ makes it easy for you and your patients

Fill out the Recorlev Prescription Start Form available at **StartRecorlev.com**

Fax the form and any relevant medical documentation to PANTHERx Rare Pharmacy at **1-866-990-4540**

PANTHERx Rare Pharmacy assists with prior authorizations, schedules shipment of Recorlev directly with your patient, and provides information to the office on access and reimbursement

**Call 1-844-444-RCLV (7258) for more information**

### Selected Important Safety Information

**CONTRAINDICATIONS**

- Cirrhosis, acute liver disease or poorly controlled chronic liver disease, baseline AST or ALT > 3 times the upper limit of normal, recurrent symptomatic cholelithiasis, a prior history of drug induced liver injury due to ketoconazole or any azole antifungal therapy that required discontinuation of treatment, or extensive metastatic liver disease.
- Taking drugs that cause QT prolongation associated with ventricular arrhythmias, including torsades de pointes.
- Prolonged QTcF interval > 470 msec at baseline, history of torsades de pointes, ventricular tachycardia, ventricular fibrillation, or prolonged QT syndrome.
- Known hypersensitivity to levoketoconazole, ketoconazole, or any excipient in Recorlev.
- Taking certain drugs that are sensitive substrates of CYP3A4 or CYP3A4 and P-gp.

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# Xeris CareConnection™ makes sure patients are getting the savings they need

xeris Care Connection™

## Eligible patients may pay as little as $0 for their prescription*

- Xeris is committed to supporting patient access to Recorlev® through the Recorlev Co-pay Savings Program, which may help to lower your patient's out-of-pocket costs
- Xeris CareConnection is available to verify patient eligibility and enroll patients in the Recorlev Co-pay Savings Program
- Visit **Recorlev.com/copay** for more information

Xeris CareConnection hours of operation are Monday through Friday from 8 AM to 7 PM ET.
Call Xeris CareConnection at **1-844-444-RCLV (7258)** for more information.

*Eligible patients pay as little as $0 with a maximum annual savings of $10,000. The authorized specialty pharmacy will activate the co-pay card for eligible patients and apply for each prescription until the annual maximum has been reached. This card is not valid for prescriptions that may be reimbursed under a federal or state healthcare program, including Medicare, Medicaid, or any other similar federal or state healthcare program, including any state pharmacy assistance program.

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# Individualize Recorlev® dosing for each patient[1]

## Recommended dosing guidance

Correct hypokalemia and hypomagnesemia, and obtain baseline ECG and liver tests before starting Recorlev.

### TABLET STRENGTH (mg)


Maximum recommended dose of four 150-mg tablets taken BID

### 1 Initiate

**150 mg**
BID

**Taken with or without food**

### 2 Titrate

**Individualized to achieve UFC normalization**

- 150 mg daily, no more frequently than every 2-3 weeks based on 24-hour UFC levels and patient tolerability
- Maximum recommended daily dose of 1200 mg (4 X 150 mg tablets BID)

### 3 Maintain

**Flexible maintenance dosing**

- Once the maintenance dosage is achieved, monitor cortisol levels from at least two 24-hour UFC collections at least every 1–2 months or as indicated
- The dose can be lowered to 150 mg orally once daily if needed for tolerability reasons

- Stay in control by monitoring your patient's cortisol levels approximately every 2 weeks until an adequate response has been achieved. Then monitor at least every 1–2 months or as indicated

**A clinical pharmacist is available to support you in the management of dose modifications. Call 1-844-444-RCLV (7258) for support.**

BID=twice daily; ECG=electrocardiogram; UFC=urinary free cortisol.

### Selected Important Safety Information

### WARNINGS AND PRECAUTIONS

Hepatotoxicity

Serious hepatotoxicity has been reported in patients receiving Recorlev, irrespective of the dosages used or the treatment duration. Drug-induced liver injury (peak ALT or AST greater than 3 times upper limit of normal) occurred in patients using Recorlev. Avoid concomitant use of Recorlev with hepatotoxic drugs. Advise patient to avoid excessive alcohol consumption while on treatment with Recorlev. Routinely monitor liver enzymes and bilirubin during treatment.

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# Clinically driven monitoring[1]

### Before initiating treatment

- Conduct baseline liver tests (ALT, AST, and total bilirubin)
- Obtain a baseline ECG
- Correct hypokalemia and hypomagnesemia

### Continued monitoring

- Conduct an ECG before each dose increase. After a stable dosage is established, monitor routinely for an effect on the QT interval
- Monitor 24-hour UFC, morning serum or plasma cortisol, and patient's signs and symptoms for hypocortisolism periodically during Recorlev® treatment

### Liver tests

- Serious hepatotoxicity has been reported in patients receiving Recorlev, and therefore frequent monitoring of liver tests is recommended
- Monitor liver enzymes and bilirubin weekly for at least 6 weeks after starting Recorlev, every 2 weeks for the next 6 weeks, monthly for the next 3 months, and then as clinically indicated
- After any dose interruption or dose increase, monitor on a weekly basis until a stable dosage is achieved

See Full Prescribing Information for dosage management and modification across AST/ALT and total bilirubin values.

ALT=alanine aminotransferase; AST=aspartate aminotransferase.

**Selected Important Safety Information**

**WARNINGS AND PRECAUTIONS (cont.)**

QT Prolongation

Use Recorlev with caution in patients with other risk factors for QT prolongation, such as congestive heart failure, bradyarrhythmias, and uncorrected electrolyte abnormalities, with more frequent ECG monitoring considered. Routinely monitor ECG and blood potassium and magnesium levels during treatment.

Hypocortisolism

Recorlev lowers cortisol levels and may lead to hypocortisolism with a potential for life-threatening adrenal insufficiency. Lowering of cortisol levels can cause nausea, vomiting, fatigue, abdominal pain, loss of appetite, and dizziness. Significant lowering of serum cortisol levels may result in adrenal insufficiency that can be manifested by hypotension, abnormal electrolyte levels, and hypoglycemia. Routinely monitor 24-hour urine free cortisol, morning serum or plasma cortisol, and patient's signs and symptoms for hypocortisolism during treatment.

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# Xeris CareConnection™ provides your patients and your office with unparalleled one-on-one support throughout the treatment journey

## Partnering with you and your office

### Core specialty pharmacy services

- Benefit verification, prior authorization, and appeal services for your office
- Proactive refill management

### Dedicated case managers

- Help your staff track patient initiation and relay information to your office

**Call 1-844-444-RCLV (7258) for support**

**Selected Important Safety Information**

**WARNINGS AND PRECAUTIONS (cont.)**

Hypersensitivity Reactions

Hypersensitivity to Recorlev has been reported. Anaphylaxis and other hypersensitivity reactions including urticaria have been reported with oral ketoconazole.

Risks Related to Decreased Testosterone

Recorlev may lower serum testosterone in men and women. Potential clinical manifestations of decreased testosterone concentrations in men may include gynecomastia, impotence and oligospermia. Potential clinical manifestations of decreased testosterone concentrations in women include decreased libido and mood changes.

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## Support for patients and caregivers

### Financial assistance

- Access and support for patients with and without insurance

**$0 co-pay program for eligible commercial patients**

### Filling prescriptions

- Convenient, free specialty pharmacy services, including 24/7 support and home delivery of Recorlev®

### Treatment reminders

- PANTHERx Rare Pharmacy delivers Recorlev directly to your patients with simple refill reminders to help them stay on track

### Specialized ongoing support

- Clinical pharmacists who specialize in endocrinology products and regularly check in with your patient directly

### Dedicated Patient Access Managers (PAMs)

- Provide personal support to patients as they take Recorlev
- Ongoing education about Cushing's syndrome and treatment with Recorlev

### Free courier service

- Free, convenient, and discreet transport of UFC lab tests available to all patients

**Selected Important Safety Information**

**ADVERSE REACTIONS**

Most common adverse reactions (incidence > 20%) are nausea/vomiting, hypokalemia, hemorrhage/contusion, systemic hypertension, headache, hepatic injury, abnormal uterine bleeding, erythema, fatigue, abdominal pain/dyspepsia, arthritis, upper respiratory infection, myalgia, arrhythmia, back pain, insomnia/sleep disturbances, and peripheral edema.

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# A comprehensive support system for you and your patients

- 24/7 support and home delivery of Recorlev® exclusively from PANTHERx Rare Pharmacy, the first national pharmacy to hold an accredited distinction in rare disease
- Xeris CareConnection™ provides one-on-one support through PAMs who regularly check in with your patient directly and clinical pharmacists who specialize in endocrinology products for the management of dose adjustments
- Financial assistance with support for patients with and without insurance and a $0 co-pay program for eligible commercial patients

**Call 1-844-444-RCLV (7258)**
**for more information**

## Selected Important Safety Information

### DRUG INTERACTIONS

- Consult approved product labeling for drugs that are substrates of CYP3A4, P-gp, OCT2, and MATE prior to initiating Recorlev.
- Sensitive CYP3A4 or CYP3A4 and P-gp Substrates: Concomitant use of Recorlev with these substrates is contraindicated or not recommended.
- Atorvastatin: Use lowest atorvastatin dose possible and monitor for adverse reactions for dosages exceeding 20 mg daily.
- Metformin: Monitor glycemia, kidney function, and vitamin B12 and adjust metformin dosage as needed.
- Strong CYP3A4 Inhibitors or Inducers: Avoid use of these drugs 2 weeks before and during Recorlev treatment.
- Gastric Acid Modulators: See Full Prescribing Information for recommendations regarding concomitant use with Recorlev.

### USE IN SPECIFIC POPULATIONS

Lactation: Advise not to breastfeed during treatment and for one day after final dose.

**Please see Full Prescribing Information, including Boxed Warning.**

**Reference: 1.** Recorlev. Prescribing information. Xeris Pharmaceuticals, Inc; 2021.

xeris® PHARMACEUTICALS



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