

**MEDICATION GUIDE**  
**RECORLEV®** (re kor ' lev)  
(levoketoconazole)  
tablets, for oral use

**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 any of the following signs or symptoms:**

- pain on the upper right side of your stomach area (abdomen) associated with nausea
- unusual fatigue
- yellowing of your skin or the whites of your eyes (jaundice)
- unusual bruising or bleeding

RECORLEV should not be used if you have any of the following conditions:

- cirrhosis
- active or poorly controlled liver disease
- frequent stones in your gallbladder (cholelithiasis)
- 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 (abdomen)
- loss of appetite
- body aches
- dizziness
- low blood pressure (hypotension)
- abnormal electrolyte levels
- low blood sugar (hypoglycemia)

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

**What is RECORLEV?**

- RECORLEV is a prescription medicine used to treat high cortisol (endogenous hypercortisolemia) levels in adult patients with Cushing's syndrome (CS) who cannot have surgery or who have had surgery that did not cure their Cushing's syndrome.
- It is not known if RECORLEV is safe and effective for the treatment of fungal infections. RECORLEV is not to be used for treatment of fungal infections.

**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 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. See the end of this Medication Guide for a complete list of ingredients in RECORLEV.
- take certain medicines that may affect how your liver works (for example, CYP3A4 inhibitors). If you are not sure if you take these medicines, please 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. RECORLEV may harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with RECORLEV or think you might be pregnant.
- are breastfeeding or plan to breastfeed. RECORLEV can pass into your breast milk. You and your healthcare provider should decide if you should take RECORLEV or breastfeed. You should **not** breastfeed during treatment with RECORLEV and for 1 day after final dose.

**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. RECORLEV may affect the way other medicines work, and other medicines may affect how RECORLEV works.

#### **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.
- RECORLEV is taken by mouth 2 times a day, with or without food.
- Your healthcare provider may decrease, temporarily hold, or permanently stop your treatment with RECORLEV if needed.
- 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:**

- See "**What is the most important information I should know about RECORLEV?**"
- **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.
- **Risks related to decreased testosterone.** RECORLEV may lower testosterone levels in males and females. Call your healthcare provider if you have any of these symptoms:
  - Males: breast enlargement (gynecomastia) and erectile dysfunction (impotence)
  - Females: low desire for sex (decreased libido) and mood changes.

**The most common side effects of RECORLEV include** nausea/vomiting, hypokalemia (low potassium), hemorrhage (easy bleeding)/contusion (easy bruising), high blood pressure, headache, liver injury, abnormal uterine bleeding, erythema (redness of the skin), fatigue, abdominal pain/dyspepsia (upset stomach), arthritis, upper respiratory infection, myalgia (muscle pain), abnormal heart rhythm, back pain, sleep disturbances, and peripheral edema (fluid retention). RECORLEV may cause fertility problems in females and males, 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.

#### **How should I store RECORLEV?**

- Store RECORLEV at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep RECORLEV and all medicines out of the reach of children.**

#### **General information about the safe and effective use of RECORLEV.**

Medications are sometimes prescribed for purposes other than those listed in this Medication Guide. Do not use RECORLEV for a condition for which it was not prescribed. Do not give RECORLEV to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about RECORLEV that is written for health professionals.

#### **What are the ingredients in RECORLEV?**

**Active ingredients:** levoketoconazole.

**Inactive ingredients:** colloidal silicon dioxide, lactose monohydrate, magnesium stearate, modified corn starch, and silicified microcrystalline cellulose.

Distributed by: Xeris Pharmaceuticals, Inc., Chicago, IL 60607

For more information, go to [www.Recorlev.com](http://www.Recorlev.com) or call 1-877-937-4737.