



CuvriorTM

300 mg
TABLETS

trientine tetrahydrochloride

The first innovative treatment for Wilson Disease in over 30 years

INDICATION

CUVRIOR is used to treat adults with stable Wilson Disease who are de-coppered and able to take penicillamine. CUVRIOR is a chelating agent which binds copper, helping your organs release copper into your bloodstream and then eliminated in your urine.¹

 **Orphalan** | Innovation
for Orphan
Diseases

Welcome to CUVRIOR

The contents of this brochure will provide you with information on:

- Wilson Disease and what it is.
- Why and how CUVRIOR is used to treat Wilson Disease in stable patients who are de-coppered and tolerant to penicillamine. Please see additional Important Safety Information on the last page.
- The patient support programs that are available to help get started on CUVRIOR.

Further information can be found by visiting www.cuvrior.com or by scanning the QR code.



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About Wilson Disease

Definition:

Wilson Disease is genetic disorder characterized by the gradual accumulation of copper in the organs, including the liver and brain.²

Causes:

Approximately 1 in every 30,000 people have a mutation which stops their liver cells from being able to effectively remove copper from the body.²

Symptoms:

Symptoms can include scarring of the liver (cirrhosis), tremors, speech difficulties, migraine headaches and insomnia. The kidney and bones can also be affected, potentially causing kidney stones or arthritis. Dark rings in the iris (colored part) of the eyes or cataracts may occur in some people.²

Treatment:

The goal of treatment is to maintain copper levels within acceptable levels in the body. Treatment is a combination of dietary changes and administration of chelating medicines (such as CUVRIOR) or zinc salts.²

Some individuals with Wilson Disease find it difficult to stick to treatment due to side effects and complex dosing routines.³

CUVRIOR is the first innovative treatment in Wilson Disease in over 30 years, bringing the advantages of an innovative formulation of trientine tetrahydrochloride, with flexibility in dosing for patients.¹

About CUVRIOR

CUVRIOR is a prescription medicine indicated for the treatment of adult patients with stable Wilson Disease who are de-coppered and tolerant to penicillamine.¹

The trientine in the tablets binds to (chelates) the copper deposits in your body, removing the excess copper in the urine. It also works by binding to, and preventing the uptake of copper in the gut from the food and drink that you consume.¹

Each box of CUVRIOR that you are provided with holds nine smaller child-resistant cartons, each containing a blister-pack of 8 tablets, giving a total of 72 tablets per large box.¹

Why CUVRIOR?

CUVRIOR tablets are:^{1,4,5}

- **Small** and easy to swallow.
- **Scored**, meaning you can break the tablets in half, allowing your healthcare provider to prescribe a personalized dose for you.
- **Stable at room temperature**, so you don't have to worry about storing your treatment in a refrigerator or transporting it in a cooler.
- **Proven to be as effective as D-penicillamine**, in stable patients who are de-coppered and tolerant to penicillamine.
- The most common side effects associated with CUVRIOR are pain in the abdomen, change in bowel habits, rash, hair loss (alopecia), and mood swings.

SELECT SAFETY INFORMATION

- **Do not use** CUVRIOR if you are allergic to trientine or to any of the ingredients in CUVRIOR.
- **Your Wilson Disease symptoms could get worse when you start treatment.** This could happen because too much copper is removed from the body in a short period of time. Your doctor may need to reduce your dose or stop CUVRIOR treatment.

Please see additional Important Safety Information on the last page.

How to Take CUVRIOR

Your healthcare provider will tell you your daily dose of CUVRIOR. The recommended CUVRIOR starting dose is 300 mg daily up to 3,000 mg taken orally in divided doses (two times daily), but this may fluctuate throughout your treatment journey depending on how well it is working. The dose should never exceed 3,000 mg per day. You may need to cut a tablet in half to reach your prescribed dose, but they should never be crushed, chewed, or dissolved before taking CUVRIOR.¹

Do not remove CUVRIOR tablets from the blister pack until it is time to take your dose, to prevent damage to the tablets and possible underdosing.¹

Tablets should be taken on an empty stomach, as food, drink and other medicines may interfere with the effectiveness of CUVRIOR. Therefore, it is important to take your prescribed dose at least 1 hour before or 2 hours after main meals, and at least 1 hour apart from other food (snacks), milk, or other orally administered medicines.¹

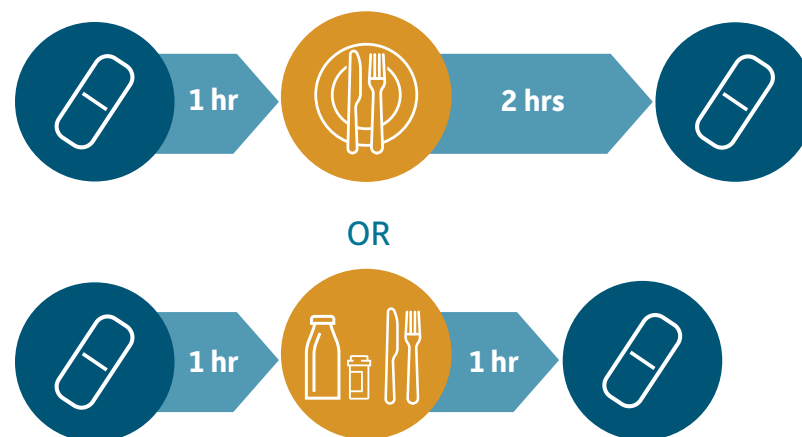


SELECT SAFETY INFORMATION

- **Copper deficiency** may develop following treatment with CUVRIOR. Your doctor will do tests to monitor your urine and blood for copper.
- **Iron deficiency** may develop while taking CUVRIOR. If this happens, your doctor may tell you to take iron supplements for a limited time.
- **Allergic reactions**, such as a rash, have been reported with trientine, the active ingredient in CUVRIOR. If a rash or other allergic reaction occurs, stop taking CUVRIOR and get emergency medical help.
- The most common side effects are pain in the abdomen, change in bowel habits, rash, hair loss (alopecia), and mood swings.

Please see additional Important Safety Information on the last page.

Take CUVRIOR at least 1 hour before or 2 hours after a large meal...



... at least 1 hour before or after other oral drugs, milk, or snacks.

SELECT SAFETY INFORMATION

- Take CUVRIOR at least 1 hour apart from any other oral medicine.
- Tell your doctor about all the medicines you're taking, including over-the-counter medicines, vitamins, and herbal supplements.
- Avoid taking supplements when taking CUVRIOR. Taking CUVRIOR with mineral supplements (e.g., iron, zinc, calcium, magnesium) can reduce the effectiveness of CUVRIOR. If iron supplementation is necessary, take CUVRIOR at least 2 hours before or 2 hours after taking iron; for other mineral supplements (e.g., zinc, calcium, magnesium), take CUVRIOR at least 1 hour before or 2 hours after.
- Do not start or stop any medicines while taking CUVRIOR without talking to your doctor.

Please see additional Important Safety Information on the last page.

Important Things to Remember

- Your Wilson Disease symptoms can worsen if you don't stick to your prescribed treatment and dietary requirements.²
- Carefully follow the dosing for CUVRIOR explained by your healthcare provider.
- Follow the dietary changes discussed with your healthcare provider.
- Store CUVRIOR at a controlled room temperature of 68°F to 77°F, brief spells between 59°F and 86°F are permitted.¹
- Speak to your healthcare provider if you have any questions or concerns.

Frequently Asked Questions*

What can I expect when I start taking CUVRIOR?

When starting CUVRIOR for the first time, your symptoms may get worse as too much copper can be removed from your body in a short time. Your doctor may reduce your dose or stop treatment with CUVRIOR.¹

Can I take CUVRIOR if I am pregnant or breast feeding?

There is no data on CUVRIOR use in pregnancy or with breastfeeding. Please consult your Wilson Disease specialist and your obstetrician.¹

What should I do if I miss a dose?

It is important to take your daily dose as advised by your healthcare professional. Missing your doses could potentially lead to a worsening of your symptoms. If you are having difficulties taking your medication every day as instructed, then please speak to your healthcare professional.

How should I store CUVRIOR?

CUVRIOR should be stored at a controlled room temperature of 68°F to 77°F, but short periods of time at between 59°F and 86°F are permitted.¹

I have experienced a side effect – how do I report this?

To report SUSPECTED ADVERSE REACTIONS, call Orphalan at 1-800-961-8320 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

*The information provided here should not take the place of professional medical advice. If you have any questions, please speak with your healthcare provider.



Navigator Program™

Patient Support by Orphalan

From start to finish, you will be able to rely on your dedicated Care Coordinator to help you:

- Get started on therapy while the pharmacy and your healthcare professional work with your insurance plan to obtain ongoing coverage.
- Understand your insurance coverage for CUVRIOR™ (trientine tetrahydrochloride).
- Understand the processes required by your insurance to access CUVRIOR (such as Prior Authorizations).
- Get information related to Co Pay and/or financial assistance programs that may be available for them.

Offerings available to you through the program include:

- **Dedicated Care Coordinator Support**
Getting started on a speciality medication can be challenging. A dedicated Care Coordinator is trained to help you navigate this process, providing you with education and support about how to access your medication.
- **Quick Start Program**
You may experience insurance related delays – this offering in the Navigator Program may be able to help you get started on treatment while you sort out insurance related questions. Enrollment and eligibility review required.
- **Co Pay Program***
Eligible patients may pay as little as \$0 per month for CUVRIOR. Commercially insured patients with a valid prescription for CUVRIOR may be eligible to participate in this program.
- **Patient Assistance Program**
Uninsured or no coverage for CUVRIOR through your insurance? Financial concerns related to high out-of-pocket expenses? The Patient Assistance Program may be able to help! Enrollment and financial assessment required to confirm eligibility.

*Terms and conditions apply.



To find out more, contact a
Care Coordinator today on
1-877-995-ORPH (6774)!

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IMPORTANT SAFETY INFORMATION

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- **Iron deficiency** may develop while taking CUVRIOR. If this happens, your doctor may tell you to take iron supplements for a limited time.
- **Allergic reactions**, such as a rash, have been reported with trientine, the active ingredient in CUVRIOR. If a rash or other allergic reaction occurs, stop taking CUVRIOR and get emergency medical help.
- **The most common side effects** are pain in the abdomen, change in bowel habits, rash, hair loss (alopecia), and mood swings.

Take CUVRIOR at least 1 hour apart from any other oral medicine. Tell your doctor about all the medicines you're taking, including over-the-counter medicines, vitamins, and herbal supplements. Avoid taking supplements when taking CUVRIOR. Taking CUVRIOR with mineral supplements (e.g., iron, zinc, calcium, magnesium) can reduce the effectiveness of CUVRIOR. If iron supplementation is necessary, take CUVRIOR at least 2 hours before or 2 hours after taking iron; for other mineral supplements (e.g., zinc, calcium, magnesium), take CUVRIOR at least 1 hour before or 2 hours after. Do not start or stop any medicines while taking CUVRIOR without talking to your doctor.

These are not all the possible side effects of CUVRIOR. You are encouraged to report negative side effects of prescription drugs. Contact Orphalan at **1-800-961-8320** or FDA at **1-800-FDA-1088** or www.fda.gov/medwatch.

Please refer to full Prescribing Information provided.

References: 1. CUVRIOR Prescribing Information. 2. Roberts E A, et al. Hepatology. 2008;47(6):2089-2111. 3. Miloh T, Graper M, Schilsky M. Adv Rare Dis. 2018;4(1):1-7. 4. Schilsky M L, et al. Lancet Gastroenterol Hepatol. 2022;7(12):1092-1102. 5. Weiss K H, et al. Eur J Drug Metab Pharmacokinet. 2021;46(5):665-675.

