

Product Specifications

Generic Name:	Trientine Hydrochloride
Brand Name:	Triokris™
Strength:	250 mg
Dosage Form:	Hard Gelatin Capsule
Route of Use:	Oral
Therapeutic Class:	Chelating Agent / Critical Care
Indication:	Wilson's Disease
Packaging:	100 Capsules
Shelf Life:	24 Months
Standards:	USP
Storage:	Store below 25°C, protected from moisture & light
Company:	Ikris Pharma Network Pvt. Ltd., India

Product Overview

Triokris™ is a generic version of Trientine Hydrochloride 250 mg, developed and manufactured in a USFDA-approved facility by Ikris Pharma Network Pvt. Ltd., India. This medicine is available in India for the management of Wilson's Disease, a rare genetic disorder that causes toxic copper accumulation in the most important organs, like the liver, brain, and eyes.

Triokris binds excess copper and enhances its urinary excretion, helping restore copper balance and prevent long-term organ damage. It is widely recognized as a safe and effective alternative to D-Penicillamine, suitable for long-term therapy.

Dosage and Administration

- Adults (≥13 years): The initial dose is 750 to 1250 mg per day, divided into two, three, or four doses daily.
- Children (≤12 years): The initial dose is 500 to 750 mg per day, given in divided doses two to four times daily.
- Maximum dose: Up to 2000 mg/day for adults and 1500 mg/day for pediatric patients aged 12 years or under.

- Take Trientine Hydrochloride Capsules on an empty stomach, at least one hour before meals or two hours after meals.
- Maintain at least a one-hour gap between Triokris and any other medication, food, or milk.
- Capsules should be swallowed whole with water – do not open or chew the capsules.
- Maintain consistent dosing times each day to ensure steady copper control and effective treatment results.

Safety Information:

Adverse Reactions:

Clinical experience with Trientine 250 mg USP has been limited. However, certain adverse reactions have been reported in clinical studies and post-marketing use.

Adverse Reactions Reported in Clinical Studies (Wilson's Disease Patients):

- Iron deficiency
- Systemic lupus erythematosus (autoimmune reaction; see Clinical Pharmacology section)

Adverse Reactions Reported in Marketed Use:

- **Dystonia** (involuntary muscle contractions)
- Muscular spasm
- **Myasthenia gravis** (muscle weakness due to impaired nerve–muscle communication)

Adverse Event Reporting:

If you experience or observe any side effects, adverse reactions, or product quality issues associated with **Triokris (Trientine Hydrochloride 250 mg)**, please report them to our **Pharmacovigilance team**. Reports will be handled confidentially and reviewed by our pharmacovigilance team in accordance with global regulatory requirements.

Serious Warnings:

Limited Clinical Experience: Patient experience with Trientine Hydrochloride is limited. Continuous clinical supervision is essential during therapy to monitor safety, response, and potential side effects.

- **General Precautions:** No hypersensitivity seen in patients, but rare asthma or skin reactions reported in industrial exposure. Monitor for allergic or respiratory symptoms.

- **Accidental Exposure:** In case of accidental skin exposure to capsule contents, wash the affected area immediately with water.
- **Initial Treatment Monitoring:** During the first month of therapy, patients should monitor their temperature nightly and promptly report any fever, rash, or skin eruption to a physician.
- **Free Copper Monitoring:** The most reliable indicator of treatment effectiveness is the free copper concentration in serum, calculated as: Total Copper – (Ceruloplasmin × 3). Adequately treated patients typically have less than 10 mcg/mL of free copper in serum.
- **Urinary Copper Excretion:** A 24-hour urinary copper test is recommended every 6–12 months. Urine should be collected in copper-free glassware. A negative copper balance of 0.5–1.0 mg/day indicates effective copper removal.
- **Iron Deficiency:** If iron deficiency develops, a short course of iron supplementation may be prescribed under medical supervision. Iron should not be taken simultaneously with Trientine, as both interfere with each other's absorption.

Drug Interactions:

Iron or Mineral Supplements: Avoid concurrent intake as they reduce Trientine absorption.

Food and Milk: Allow at least a one-hour gap, as they decrease absorption efficiency.

Zinc or Other Copper Chelators: Use only under the supervision of a specialist.

Nutritional Monitoring:

Low-Copper Diet: Maintain a low-copper diet (less than 1 mg/day) to enhance therapeutic outcomes.

Iron Monitoring: Periodically check serum iron levels, especially in children, menstruating women, and pregnant women.

Caution & Prescription Note:

- Keep out of reach of children.
- Swallow capsules whole; do not chew or crush.
- Store in a cool, dry, dark place below 25 °C.
- Dosage should always be as directed by the treating physician.

About Ikris Pharma Network

With our headquarters in India and a global presence spanning Belgium, Hong Kong, and Bulgaria, Ikris Pharma Network Pvt. Ltd. is a leading global pharmaceutical company specializing in Named Patient Import Programs, Rare Disease Medicines, and Global Pharmaceutical Import/Export.

We are known for delivering high-quality medicines to over 100 countries across Europe, the Pacific Region, Latin America, Southeast Asia, Central Asia, the Middle East, and Africa.

We specialize in the global distribution of essential, hard-to-access, and specialty medications, supporting importers, distributors, and wholesalers in critical therapeutic areas like advanced oncology care, Nephrology, Haematology, Cardiology, and infectious disease management.

Frequently Asked Questions (FAQ)

1. What is Wilson's disease?

Wilson's Disease (also known as hepatolenticular degeneration) is a rare genetic disorder caused by mutations in the **ATP7B gene**, leading to abnormal copper accumulation in vital organs like the liver, brain, and cornea.

Trientine Hydrochloride, the active ingredient in **Triokris**, is a copper-chelating agent that binds excess copper and helps remove it naturally through urine, preventing further organ damage.

2. Where can I buy Trientine online in India?

You can legally **buy Trientine online in India** through **Ikris Pharma Network**, the manufacturer and supplier of **Triokris (Trientine Hydrochloride 250 mg)**. We ensure global-quality standards and regulatory compliance for **Importers, Wholesalers, Distributors, Hospitals, NGOs, and Patient Assistance Programs (PAPs)**.

3. How quickly does Triokris start working?

Triokris begins to lower copper levels within weeks, but noticeable clinical improvements may take several months' continuous use as body copper levels gradually decrease. Clinical improvement depends on baseline copper burden and liver involvement.

4. Can Triokris cure Wilson's disease?

No. Wilson's disease is not curable, but it is effectively manageable with lifelong treatment. Triokris helps control the accumulation of copper and prevent complications.

5. What should I do if I miss a dose?

Take the missed dose as soon as you remember, unless it is almost time for your next scheduled dose. Do not double-dose to make up for a missed one.

6. Can children take Triokris?

Yes. Triokris is approved for use in pediatric patients under medical supervision, with dose adjustments based on body weight.

7. Are there any dietary restrictions while taking Triokris?

Yes. Patients should avoid high-copper foods such as shellfish, nuts, chocolate, mushrooms, and organ meats. A low-copper diet is recommended during therapy.

8. Can pregnant or breastfeeding women take Triokris?

Triokris should be used during pregnancy only if clearly needed and under medical supervision. It is not known whether it passes into breast milk. Consult your physician before use.

9. What is the difference between Triokris and other copper chelating agents?

- **Triokris:** Well-tolerated alternative to D-penicillamine with fewer allergic and dermatological side effects.
- **D-Penicillamine:** Traditionally first-line but associated with more adverse effects.
- **Zinc therapy:** Used as maintenance or combination therapy to block copper absorption.

10. How long will I need to take Triokris?

Wilson's disease requires lifelong treatment. Stopping medicine can cause rapid copper accumulation and liver or neurological damage.

11. Are there any laboratory tests I need while taking Triokris?

Yes. Regular copper studies, liver function tests, CBC, and urine copper levels are mandatory to adjust therapy safely.

12. Can Triokris be taken with other Wilson's disease medications?

Yes, in some cases, Triokris may be used in combination with zinc salts or antioxidant supplements under medical guidance.

13. Is genetic testing available for family members?

Yes. Genetic testing for ATP7B mutations is available and recommended for siblings and first-degree relatives of affected patients.

14. Who is the trusted Trientine manufacturer and supplier from India?

Ikris Pharma Network Pvt. Ltd. is a leading Trientine manufacturer, supplier, and exporter in India. We provide Triokris (Trientine Hydrochloride 250 mg) to **Importers, Wholesalers, Distributors, Hospitals, NGOs,** and **Patient Assistance Programs (PAPs)**, ensuring 100% traceable, GDP-compliant logistics.

15. Why choose Trientine from a US FDA-approved manufacturing plant?

Triokris is manufactured in a **US FDA-approved and WHO-GMP-certified facility** in India. This ensures each batch meets **global standards for purity, potency, and safety**, backed by complete regulatory documentation.