

# Cuprior

***trientine (as tetrahydrochloride)***

150 mg film-coated tablets

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## What is in this leaflet

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Please read this leaflet carefully before you start using Cuprior.

This leaflet answers some common questions about Cuprior. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Cuprior against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

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## What Cuprior is used for

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Cuprior is a medicine used to treat Wilson's disease that contains the active substance trientine.

Wilson's disease is an inherited condition in which the body cannot transport copper around the body in the normal way or remove copper in the normal way as a secretion from the liver into the gut. This means that the small amounts of copper from food and drink build up to excessive levels and can lead to liver damage and problems in the nervous system. This medicine mainly works by attaching to copper in the body which then allows it to be removed in the urine instead, helping to lower copper levels. It may also attach to copper in the gut and so reduce the amount taken up into the body.

Cuprior is given to adults, adolescents and children aged 5 years and over who cannot tolerate another medicine that is used to treat this disease, called penicillamine.

Your doctor may have prescribed Cuprior for another reason.

Ask your doctor if you have any questions about why Cuprior has been prescribed for you.

This medicine is available only with a doctor's prescription.

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## **Before you use Cuprior**

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### ***When you must not use it***

Do not use Cuprior if:

- If you are allergic to trientine or any of the other ingredients of this medicine (listed in section 6).

If you are not sure whether you should start using Cuprior, talk to your doctor.

### ***Before you start to use it***

Talk to your doctor or pharmacist before taking Cuprior.

If you were already taking another trientine medicine, your doctor may modify your daily dose, the number of tablets or the number of intake in the day when switching to Cuprior treatment.

Your symptoms may initially get worse after starting the treatment. If this happens, you must tell your doctor.

Your doctor will regularly check your blood and urine to ensure that you receive the right dose of Cuprior to properly control your symptoms and copper levels.

You should tell your doctor if you get any side effects as this may indicate that your dose of Cuprior needs to be adjusted up or down.

This medicine may also reduce the level of iron in your blood and your doctor may prescribe iron supplements (see section "Other medicines and Cuprior" below).

If you have kidney problems, your doctor will regularly check that the treatment dose is appropriate and does not affect the functioning of your kidney.

The association of trientine with another medicine that contains zinc is not recommended.

Lupus-like reactions (symptoms may include persistent rash, fever, joint pain, and tiredness) have been reported in some patients switched to trientine medicine after

penicillamine medicine. However it was not possible to determine if the reaction was due to trientine or to previous penicillamine treatment.

#### *Children and adolescents*

Your doctor will carry out checks more frequently to ensure your copper levels are maintained at a suitable level for normal growth and mental development.

This medicine is not recommended for children aged below 5 years of age.

### ***Taking other medicines***

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Cuprior.

In particular, you must tell your doctor if you are already taking iron supplements or if you take indigestion remedies (medicines that reduce discomfort after eating).

If you take these medicines, you may need to take Cuprior at a different time in the day because otherwise Cuprior may not be as effective. If you take iron supplements, make sure that at least two hours have passed between taking Cuprior and taking your iron supplements.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Cuprior.

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## **How to use Cuprior**

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### ***How to take Cuprior***

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

In adults of all ages, the recommended total daily dose is 3 to 6½ tablets per day (making a total of between 450 and 975 mg). This daily total will be divided into 2 to 4 smaller doses to be taken during the day. Your doctor will tell you how many tablets you should take and how often in the day.

Tablets can be divided in half if needed.

### ***Use in children and adolescents***

The dose that you will take is usually lower than for an adult and depends on your age and body weight.

The usual total daily dose is between 225 and 600 mg (1½ to 4 tablets daily), which will be divided into 2 to 4 smaller doses to be taken during the day. Your doctor will tell you how many tablets you should take and how often in the day.

Once you have started the treatment, your doctor may adjust the dose based on the response to treatment.

Swallow the tablets with water on an empty stomach, at least one hour before meals or two hours after meals and at least one hour apart from any other medicines, food, or milk.

If you take iron supplements, take them at least two hours after taking a dose of Cuprior.

### ***If you forget to take Cuprior***

Do not take a double dose to make up for a forgotten dose. Just take your next dose at its regularly scheduled time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

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## **While you are using Cuprior**

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### ***Things you must do***

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Cuprior.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

It is very important to continue treatment to reduce copper during pregnancy. You and your doctor should fully discuss the potential benefits of treatment whilst considering any possible risks that there may be. Your doctor will advise you which treatment and which dose is best in your situation.

If you are pregnant and taking Cuprior, you will be monitored throughout your pregnancy for any effects on the baby or changes in your copper levels. When your baby is born, the copper level in the baby's blood will also be monitored.

It is not known if Cuprior can pass into breast milk. It is important to tell your doctor if you are breast-feeding or plan to do so. Your doctor will then help you decide whether to stop breast-feeding or to stop taking Cuprior, considering the benefit of

breast-feeding to the baby and the benefit of Cuprior to the mother. Your doctor will decide which treatment and which dose is best in your situation.

### ***Things you must not do***

Do not give Cuprior to anyone else, even if they have the same condition as you.

This medicine is for long-term use. Do not stop your treatment without the advice of your doctor even if you feel better because Wilson's disease is a life-long condition.

### ***Things to be careful of***

Cuprior is not expected to affect your ability to drive a car or use any tools or machines.

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## **In case of overdose**

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### ***If you take too much (overdose)***

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Cuprior.

Do this even if there are no signs of discomfort or poisoning.

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## **Side Effects**

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Cuprior.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

The following side effects have been reported:

Common (may affect up to 1 in 10 people)

- feeling sick (nausea)

Uncommon (may affect up to 1 in 100 people)

- skin rashes
- itching

Not known (frequency cannot be estimated from available data)

- stomach upsets and discomfort, including severe stomach pains (duodenitis)
- inflammation of the gut which may lead to e.g. abdominal pain, recurring diarrhoea and blood in stools (colitis)
- decrease in the number of red blood cells due to low iron level in your blood (iron deficiency anaemia)
- urticaria (nettle rash or hives).

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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## After using Cuprior

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### ***Storage***

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store at or below 25°C.

### ***Disposal***

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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## Product description

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### ***What it looks like***

Yellow, 16 mm x 8 mm oblong film-coated tablet with a score line on each side. The film-coated tablet can be divided into equal doses.

OPA/Alu/PVC-Alu blisters, each blister contains 8 film-coated tablets. Pack of 72 tablets

## ***Ingredients***

### Active ingredient(s):

The active substance is trientine. Each film-coated tablet (tablet) contains trientine tetrahydrochloride equivalent to 150 mg trientine.

### Inactive ingredients:

Tablet core: mannitol, colloidal anhydrous silica and glycerol dibehenate.

Tablet film-coating: polyvinyl alcohol, talc, titanium dioxide (E171), glycerol monocaprylocaprate (Type I), iron oxide yellow (E172) and sodium laurilsulfate

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## **Sponsor Details**

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Cuprior is supplied in New Zealand by:

Te Arai BioFarma Ltd

PO Box 46205  
Herne Bay  
Auckland  
NEW ZEALAND

0800 TEARAI

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## **Date of Preparation**

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This leaflet was prepared on 6 June 2020