Package leaflet: Information for the patient
Cuprior 150 mg
film-coated tablets
trientine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed only for you. Do not pass it on to others, even if they have the same symptoms as yours, it may harm them.
- If you get any side effects, talk to your doctor or pharmacist, including possible side effects that are not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Cuprior is and what it is used for

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

Wilson disease is an inherited disease in which the body cannot transport copper in the body in the normal way or cannot remove copper in the normal way as a secretion from the liver into the gut. For this reason, the small quantities of copper ingested with food and drink keep on building up in excessive levels, which can lead to liver injuries and problems in the nervous system. This medicine works mainly by binding to copper in the body which then can be eliminated in the urine, helping to lower the copper levels. It may also bind to copper in the gut, and thus, reduce the quantity of copper absorbed by the body.
Cuprior is administered to adults, adolescents and children aged 5 years old and over who cannot tolerate another medicine used to treat this disease named penicillamine.

2. What you need to know before you take Cuprior

Do not take Cuprior
if you are allergic to trientine or to any other ingredient of this medicine (listed in section 6).

Warnings and precautions
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 your treatment to Cuprior.
Your symptoms may get worse when starting the treatment. In this case, 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 control your symptoms and copper levels.
You should tell your doctor if you get any side effect as this may indicate that it is necessary to adjust your dose of Cuprior up or down.
This medicine may also reduce the level of iron in your blood, so your doctor may prescribe you 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 that it does not affect the functioning of your kidneys.
The association of trientine with another medicine containing zinc is not recommended.

Lupus-like reactions (with symptoms like persistent skin rash, fever, joint pain and tiredness) have been reported in some patients who switched to trientine after receiving penicillamine. However, it was not possible to determine if the reaction was caused by the trientine o due to the previous treatment with penicillamine.

Children and adolescents
Your doctor will carry out check-ups more frequently to ensure that your copper levels are maintained at a suitable level for the normal growth and mental development.
This medicine is not recommended for children below 5 years old.

Other medicines and Cuprior
Tell your doctor if you are taking, have recently taken, or might take any other medicine.
In particular, you must tell your doctor if you are already taking iron supplements or if you take indigestion medicines (medicines that reduce discomfort after eating). If you are taking these medicines, you may need to take Cuprior at a different time during the day, because otherwise Cuprior may not be effective. If you take iron supplements, make sure that two hours have passed at least between taking Cuprior and taking your iron supplements.

Pregnancy and breast-feeding
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 that you continue with the treatment to reduce the copper levels during pregnancy. You should carefully discus with your doctor about the possible benefits of the treatment, taking also into account the risks that may occur. Your doctor will advise you which is the best treatment and dose in your situation.
If you are pregnant and taking Cuprior, you will undergo controls throughout your pregnancy for any effects on the baby or any change in your copper levels. When your baby is born, the copper level will also be controlled in the baby's blood.
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 it is better to discontinue the breast-feeding or to stop taking Cuprior, taking into account the benefit of breast-feeding for the baby and the benefit of Cuprior for the mother. Your doctor will decide which the best treatment is and dose in your situation.

Driving and using of machines
Cuprior is not expected to affect your ability to drive or use tools or machines.

3. How to take Cuprior

Follow exactly the administration instructions of this medicine as indicated by your doctor of pharmacist. Should you have any doubt, ask your doctor of pharmacist again.

In adults of all ages, the recommended total daily dose is 450 to 900 mg initially (3 to 6 tablets) up to a maximum of 1200 mg (8 tablets). This daily total dose will be divided in 2 to 4 smaller doses which will be taken during the day. Your doctor will indicate you how many tablets you should take and how often during the day. If necessary, the tablets can be split in half to make the administration easier.

Use in children and adolescents
The dose for children and adolescents will usually be lower than for adults and will depend on the age and body weight.
The usual total daily dose is between 300 and 450 mg initially (2 to 3 tablets) up to a maximum of 900 mg (6 tablets) which will be divided in 2 to 4 smaller doses to be taken during the day.
Your doctor will indicate you how many tablets you should take and how often during the day. If necessary, the tablets can be split in half to make the administration easier.
Once you have started the treatment, your doctor may adjust the dose depending on the response to the treatment.

Swallow the tablets with water on an empty stomach, at least one hour before 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 take more Cuprior than you should
Take Cuprior only as it is prescribed for you. If you think you may have taken more Cuprior than you were indicated, contact your doctor or pharmacist.

If you forget to take Cuprior
Do not take a double dose to make up for the forgotten one. Take your next dose at the usual time.
Should you have any doubt about the use of this medicine, ask your doctor or pharmacist.

If you stop taking Cuprior
This medicine is indicated for long-term use. Do not discontinue the treatment without the advice of your doctor, even if you feel better because Wilson disease is a life-long condition.
Should you have another doubt about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all the medicines, this medicine can cause side effects, although not everybody gets them.
The following side effects have been reported:
Common (may affect up to 1 in 10 patients)
- feeling sick (nausea)

Uncommon (may affect up to 1 in 100 patients)
- skin rashes
- itching
- anemia

Not known frequency (cannot be estimated from the available data)
- stomach upset and discomfort, such as severe stomach pain (duodenitis)
- inflammation of the gut which may cause, for example, abdominal pain, recurring diarrhea and blood in stools (colitis)
- decrease of the number of red blood cells due to a low iron level in blood (iron deficiency)
- urticarial (lumps)

Report of side effects
If you experience any type of side effect, talk to your doctor or pharmacist, even if the side effects are not listed in this package insert. You can also report side effects directly through the national pharmacosurveillance program of INVIMA, available on the entity website: www.invima.gov.co or through the email: reportefv@invima.gov.co or call to 2948700 ext. 3916-3904.
Reporting side effects, you may contribute to provide additional information about the safety of this medicine.

5. How to store Cuprior

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.
This medicine does not require special storage conditions.
The medicines should not be thrown away via wastewater or in the household waste. Ask your pharmacist how to dispose of the medicines you no longer use. In this way, you will help to protect the environment.
If necessary, the tablets can be split in half to make the administration easier. If so, keep the unused half in a fresh and dry environment, using a pill box as container, or the product original blister. Use the other half within 12 hours after the fractioning of the tablet, preferably for the next immediate dose. In case of not using the remaining fraction within 12 hour after having fractioned tablet, dispose it according the local legislation requirements.

6. Content of the pack and additional information

What Cuprior contains

The active principle is trientine. Each film-coated tablet contains trientine tetrahydrochloride equivalent to 150 mg of trientine.

The other ingredients are:

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

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

What Cuprior looks like and contents of the pack

Yellow, 16 mm x 8 mm oblong film-coated tablet with a score line on each side. The film-coated tablet can be split in half to make the administration easier.

OPA/Alu/PVC-Alu blisters, each blister contains 8 film-coated tablets. Cuprior is available in packs of 72 or 96 film-coated tablets.

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Last revision date of this package insert: 07/2021

Version No.	4	**Date:**	14-07-21	**File Name:**	Cuprior COL 150mg PIL v4.indd
Printer:	TBC	**Repro House:**	TBC	**Print Process:**	xxxx
Profile Ref: (dimensions if required):	165 x 315mm				
Substrate:	Paper	**Substrate Colour:**	White		
Country	Colombia	**Software Used:**	In Design CS5		

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