

PACKAGE LEAFLET

Package leaflet: Information for the user

Trientine 167 mg hard capsules

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 or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trientine is and what it is used for
2. What you need to know before you take Trientine
3. How to take Trientine
4. Possible side effects
5. How to store Trientine
6. Contents of the pack and other information

1. What Trientine is and what it is used for

Trientine contains trientine. This medicine is used for the treatment of Wilson's disease.

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.

Trientine 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.

It controls the amount of copper in the body by binding to it. The copper can then be passed from the body.

2. What you need to know before you take Trientine

Do not take Trientine:

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Trientine.

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

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 Trientine 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 trientine 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 Trientine” below).

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

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.

Other medicines and Trientine

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, you must tell your doctor if you are taking Iron supplements or indigestion remedies (medicines that reduce discomfort after eating). If you take these medicines you may need to take Trientine at a different time of the day because < {(Invented) name} > may not be as effective.

If you take iron supplements, make sure that at least two hours have passed between taking Trientine and taking your iron supplements.

Trientine with food and drink

Swallow the capsules 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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You and your doctor can fully discuss the potential benefits of treatment whilst considering any possible risks that there may be with continuing treatment. Your doctor will advise you which treatment and which dose is best in your situation.

If you are pregnant and taking Trientine, you will be monitored throughout pregnancy for any effects on the baby or changes in copper levels in your blood.

When your baby is born the levels of copper and ceruloplasmin in baby’s blood will also be monitored. It is not known if Trientine 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 Trientine, considering the benefit of breast-feeding to the baby and the benefit of Trientine to the mother. Your doctor will decide which treatment and which dose is best in your situation.

Driving and using machines

Trientine is not expected to affect your ability to drive or use tools or operate machinery.

Trientine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take Trientine

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 including the elderly the recommended total daily dose is between 4 and 8 capsules per day (making a total of 670-1340 mg trientine base), to be taken orally. 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 capsules you should take and how often in the day.

Use in children

The dose that you will take is usually lower than for an adult and depends on your age and body weight. The total daily dose varies between 2 and 5 capsules (330-840 mg trientine base), to be taken orally. 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 capsules 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 capsules 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 Trientine.

If you take more Trientine than you should

Take Trientine only as it is prescribed for you. If you think you may have taken more Trientine than you were told to contact your doctor or pharmacist.

If you forget to take Trientine

If you forget to take one or more doses, take another dose as soon as possible, then take next dose as per your regularly scheduled time. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Occasionally, treatment with trientine can cause inflammation of the small intestine or colon. If you experience any of the following side effects, contact your doctor **immediately**.

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
- anaemia

Not known (may affect an unknown number of people)

- 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).

If you suffer from Wilson's disease you should tell your doctor if you experience:

nervous system deterioration (for example shaking, lack of co-ordination, slurred speech, muscle stiffness, worsening of muscle spasms)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs Pharmacovigilance, website www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Trientine

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

This medicine does not require any special temperature storage conditions. Keep the bottle tightly closed in order to protect from moisture.

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

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.

6. Contents of the pack and other information

What Trientine contains

The active substance is trientine. Each hard capsule contains 167 mg trientine equivalent to 250 mg trientine dihydrochloride.

The other ingredients are:

Capsule content: anhydrous colloidal silica, stearic acid.

Capsule shell: gelatin, sodium lauryl sulphate, red iron oxide (E172), yellow iron oxide (E172), titanium dioxide (E171), *printing ink:* shellac, propylene glycol, potassium hydroxide, black iron oxide (E172).

What Trientine looks like and contents of the pack

Brown opaque hard gelatin size 1 capsule imprinted with "HP551" in black ink on the capsule body and cap. The capsule length is between 18.9 mm and 19.7 mm.

Trientine capsules are available in white opaque HDPE bottles with a PP child resistant closure.

Pack size: 100 capsules

Trientine capsules are also available in Alu-Alu blister packs.

Pack size: 30, 72, 96, 100, 240 and 300 Capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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^[1]**Only the actual release site will be listed on the marketed product**

This medicine is authorised in the Member States of the EEA under the following names:

Norway	Trientine Tillomed Pharma GmbH
Ireland	Trientine 167 mg Hard Capsules
Germany	Trientine Tillomed 167 mg Hartkapseln
Greece	Trientine/Tillomed 167 mg Καψάκιο, σκληρό
Austria	Cuivrin 167 mg Hartkapseln
Czech Republic	Trientine Tillomed
Slovakia	Trientine Tillomed 167 mg tvrdé kapsuly

This leaflet was last revised in 06/2023