

PACKAGE LEAFLET

Package leaflet: Information for the patient

Trientine dihydrochloride Tillomed 250mg capsules, hard trientine dihydrochloride

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, 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, 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
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1. What Trientine is and what it is used for

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

Trientine is given to adults, adolescents and children aged 5 years and over who cannot take another medicine, called penicillamine.

Trientine controls the amount of copper in the body by attaching to it. The excess copper can then pass from the body via urine.

The name of your medicine is Trientine dihydrochloride Tillomed 250 mg (hard) capsules, but will be referred to as Trientine throughout this leaflet.

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 when switching to treatment with Trientine.

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. Regular monitoring is especially important at the start of your treatment, when your dose is changed, in children and pregnant women. Your doctor may need to adjust your dose of Trientine.

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 combination of trientine with zinc, calcium or magnesium antacids is not recommended.

Nervous system problems can occur (shaking, lack of co-ordination, slurred speech, muscle stiffness and worsening of muscle spasms), especially if you are just starting treatment with Trientine. If you notice any of these symptoms whilst taking Trientine, tell your doctor immediately.

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.

Other medicines and Trientine

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

If you are taking iron supplements or indigestion remedies (medicines that reduce discomfort after eating), leave at least two hours before or after taking Trientine because Trientine may not be as effective.

It is recommended that Trientine is taken at least one hour apart from any other medicinal product.

Trientine with food and drink

Swallow the capsules 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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to become pregnant, ask your doctor 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 become pregnant whilst taking Trientine, talk to your doctor.

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.

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 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.

Adults (including the elderly)

The recommended dose is between 4 and 8 capsules per day, to be taken orally.

The total daily dose can be divided into 2 to 4 smaller doses. Your doctor will decide the correct dose for you.

Children and adolescents (5 to 17 years)

The dose depends on age and body weight. At the start of treatment, the dose varies between 2 and 5 capsules per day, to be taken orally.

The total daily dose can be divided into 2 to 4 smaller doses. Your doctor will decide the correct dose for you.

If you have difficulty swallowing, you should talk to your doctor.

If you take more Trientine than you should

If you think you may have taken more Trientine than you should, contact your doctor or pharmacist immediately. If you have taken more medicine than you should, you may feel or be sick (nausea, vomiting) and dizziness.

If you forget to take Trientine

If you forget to take a dose, take your next dose as per your usual scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Trientine

This medicine is intended for long-term use. Do not stop or change your treatment without speaking to your doctor, even if you feel better.

If you have any questions regarding the use of this medicinal product, contact 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**:

- severe stomach pains (duodenitis)
- persistent diarrhoea (colitis)
- nervous system problems such as shaking (tremor), lack of co-ordination, slurred speech (dysarthria), muscle stiffness, worsening of muscle spasms (dystonia)

Other side effects may include:

Common (may affect up to 1 in 10 people)

- feeling sick (nausea), especially when starting treatment

Uncommon (may affect up to 1 in 100 people)

- skin rashes
- anaemia (you may feel unusually tired)

Not known (frequency cannot be estimated from available data)

- lupus-like syndrome (symptoms may include persistent rash, fever, joint pain, and tiredness)
- inflammation of the kidneys (lupus nephritis)

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. 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 medicinal product 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 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 bottle with a PP child resistant closure: Pack size: 100 capsules

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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'only one will be listed on Package Leaflet

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