

Package leaflet: Information for the user

Wilzin 25 mg hard capsules / Wilzin 50 mg hard capsules

Zinc

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 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. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Wilzin is and what it is used for

Wilzin belongs to a group of medicines called Various Alimentary Tract and metabolism products. Wilzin is indicated in the treatment of Wilson's disease, which is a rare inherited defect in copper excretion. Dietary copper, which cannot be properly eliminated, accumulates first in the liver, then in other organs such as the eyes and the brain. This potentially leads to liver damage and neurological disorders.

Wilzin blocks the absorption of copper from the intestine thereby preventing its transfer into the blood and its further accumulation in the body. Unabsorbed copper is then eliminated in the stool.

Wilson's disease will persist during the entire lifetime of the patient and therefore the need for this treatment is life-long.

2. What you need to know before you take Wilzin

Do not take Wilzin

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Wilzin.

Wilzin is usually not recommended for initial therapy of patients with signs and symptoms of Wilson's disease because of its slow onset of action.

If you are currently treated with another anti-copper agent, for example, penicillamine, your doctor may add Wilzin before stopping the initial treatment.

As with other anti-copper agents such as penicillamine, your symptoms may get worse after starting the treatment. In this case, you must inform your doctor.

In order to follow up your condition and treatment your doctor will check your blood and urine on a regular basis. This is to ensure that you receive sufficient treatment. Monitoring may detect evidence of insufficient treatment (copper excess) or excessive treatment (copper deficiency), both of which can be harmful, particularly to growing children and pregnant women.

You should tell your doctor if you experience unusual muscle weakness or abnormal feeling in your limbs as this may indicate excessive treatment.

Other medicines and Wilzin

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

Please consult your doctor before taking any other medicines which may reduce the effectiveness of Wilzin, such as iron, calcium supplements, tetracyclines (antibiotics) or phosphorus. Conversely, the effectiveness of some medicines, such as iron, tetracyclines or fluoroquinolones (antibiotics), may be reduced by Wilzin.

Wilzin with food and drink

Wilzin should be taken on an empty stomach, separated from mealtimes. Dietary fibres and some dairy products, in particular, delay the absorption of zinc salts. Some patients experience stomach upset after the morning dose. Please discuss the matter with your Wilson's disease doctor if this affects you.

This side effect may be reduced by postponing the first dose of the day until mid-morning (between breakfast and the midday meal). It may also be minimised by taking the first dose of Wilzin with a small amount of protein-containing food, such as meat (but not milk).

Pregnancy and breast-feeding

Please consult your doctor if you plan to become pregnant. It is very important to continue anti-copper therapy during pregnancy.

If you become pregnant during therapy with Wilzin, your doctor will decide which treatment and which dose is best in your situation.

Breast-feeding should be avoided if you are on Wilzin therapy. Please discuss with your doctor.

Driving and using machines

No studies of the effects on the ability to drive and use machines have been performed.

Wilzin contains sunset yellow FCF (E110)

Wilzin 50 mg hard capsules contains sunset yellow FCF (E110) which may cause allergic reactions.

3. How to take Wilzin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. For the different dose regimens Wilzin is available in hard capsules of 25 mg or 50 mg.

- For adults:

The usual dose is 1 hard capsule of Wilzin 50 mg (or 2 hard capsules of Wilzin 25 mg) three times daily with a maximum dose of 1 hard capsule of Wilzin 50 mg (or 2 hard capsules of Wilzin 25 mg) five times daily.

- For children and adolescents:

The usual dose is:

- from 1 to 6 years: 1 hard capsule of Wilzin 25 mg twice daily
- from 6 to 16 years if bodyweight under 57 kg: 1 hard capsule of Wilzin 25 mg three times daily
- from 16 years or if bodyweight above 57 kg: 2 hard capsules of Wilzin 25 mg or 1 hard capsule of Wilzin 50 mg three times daily.

Always take Wilzin on an empty stomach, at least one hour before or 2-3 hours after meals.

If the morning dose is not well tolerated (see section 4) it is possible to delay it to mid-morning, between breakfast and lunch. It is also possible to take Wilzin with a little protein, such as meat.

If you have been prescribed Wilzin with another anti-copper agent, such as penicillamine, keep an interval of at least 1 hour between the two medicines.

To administer Wilzin to children who are unable to swallow capsules, open the capsule and mix the powder with a little water (possibly flavoured with sugar or syrup).

If you take more Wilzin than you should

If you take more Wilzin than prescribed, you may experience nausea, vomiting and dizziness. In this case you must ask your doctor for advice.

If you forget to take Wilzin

Do not take a double dose to make up for a forgotten individual dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These side effects may occur with certain frequencies, which are defined as follows:

- very common: affects more than 1 user in 10
- common: affects 1 to 10 users in 100
- uncommon: affects 1 to 10 users in 1,000
- rare: affects 1 to 10 users in 10,000
- very rare: affects less than 1 user in 10,000
- not known: frequency cannot be estimated from the available data.

Common:

- After Wilzin intake, gastric irritation may occur, especially at the beginning of treatment.
- Changes in blood tests have been reported, including an increase in some liver and pancreatic enzymes.

Uncommon:

- A decrease in blood red and white cells may occur.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system : Yellow Card Scheme, Website: 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 Wilzin

- 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 bottle and the carton, after EXP. The expiry date refers to the last day of that month.
- Do not store above 25°C.

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 Wilzin contains

The active substance is zinc. Each hard capsule contains 25 mg of zinc (corresponding to 83.92 mg of zinc acetate dihydrate) or 50 mg of zinc (corresponding to 167.84 mg of zinc acetate dihydrate).

The other ingredients are maize starch and magnesium stearate. The capsule shell contains gelatin, titanium dioxide (E171) and either brilliant blue FCF (E133) for Wilzin 25 mg, or sunset yellow FCF (E110) for Wilzin 50 mg. The printing ink contains black iron oxide (E172) and shellac.

What Wilzin looks like and contents of the pack

Wilzin 25 mg is an aqua blue hard capsule imprinted "93-376". Wilzin 50 mg is an orange opaque hard capsule imprinted "93-377".

It is available in packs of 250 hard capsules in a polyethylene bottle closed by a polypropylene and polyethylene closure. The bottle also contains a cotton filler.

Marketing Authorisation Holder and Manufacturer

Recordati Rare Diseases - Tour Hekla - 52 avenue du Général de Gaulle - F-92800 Puteaux – France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: United Kingdom Recordati Rare Diseases UK Ltd. Tel: +44 (0)1491 414333

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