European Medicines Agency

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Wilzin
zinc

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Wilzin?
Wilzin is a medicine that contains the active substance zinc. It is available as capsules (blue: 25 mg; orange: 50 mg).

What is Wilzin used for?
Wilzin is used to treat Wilson's disease. Wilson's disease is a rare inherited disorder where patients lack an enzyme that is needed to eliminate the copper contained in food from the body. This results in copper building up in the body, first in the liver, then in other organs such as the eye and the brain. This causes a variety of effects, including liver disease and damage to the nervous system.
Because the number of patients with Wilson's disease is low, the disease is considered 'rare', and Wilzin was designated an 'orphan medicine' (a medicine used in rare diseases) on 31 July 2001.
The medicine can only be obtained with a prescription.

How is Wilzin used?
Wilzin treatment should be started by a doctor who has experience in the treatment of Wilson's disease.
The usual dose for adults is 50 mg three times a day. A reduced dose is used in children. Wilzin should be taken on an empty stomach, at least one hour before or two to three hours after meals.
Wilzin is a long-term treatment. Patients who are switching from a 'chelating agent' (another type of medicine for Wilson's disease) to Wilzin should continue to take the chelating agent for two to three weeks after starting Wilzin, because Wilzin takes some time to start working fully. The maximum dose of Wilzin is 50 mg five times a day. For more information, see the Package Leaflet.

How does Wilzin work?
The active substance in Wilzin is the zinc cation (positively charged zinc), which blocks the absorption of copper from the diet. It works by stimulating the body to produce a protein called metallothionein in the cells lining the gut. This protein attaches to copper and prevents it being transferred into the blood. The copper is then passed out of the body in the stools. Over time, the amount of copper in the body falls, improving the symptoms of the disease. Zinc has been used to treat Wilson's disease since 1958.

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How has Wilzin been studied?
Because zinc has been used to treat Wilson's disease for many years, the company presented the results of studies from the published literature. In total, data to support the use of Wilzin came from 255 patients with Wilson's disease. The main study involved 148 patients who were treated with Wilzin, but did not compare Wilzin with any other treatments. The main measure of effectiveness was whether patients had adequate control of copper levels.

What benefit has Wilzin shown during the studies?
Wilzin has been shown to be effective in reducing the absorption of copper and reducing the amount of copper in the body. In the main study, 91% of the patients evaluated (91 out of 100) had adequate control of their copper levels within the first year of treatment with Wilzin.

What is the risk associated with Wilzin?
The most common side effects with Wilzin (seen in between 1 and 10 patients in 100) are gastric irritation (irritation of the stomach) and increased blood levels of enzymes (amylase, lipase and alkaline phosphatase). Gastric irritation is usually worst with the first morning dose and disappears after the first few days of treatment. Delaying the first dose to mid-morning or taking the dose with a small amount of food containing protein, such as meat, may help. For the full list of all side effects reported with Wilzin, see the Package Leaflet.
Wilzin should not be used in people who may be hypersensitive (allergic) to zinc or any of the other ingredients.

Why has Wilzin been approved?
The Committee for Medicinal products for Human Use (CHMP) noted that Wilson's disease is a fatal disease and the other medicines already being used for the disease can have severe side effects. Therefore, the Committee decided that Wilzin's benefits are greater than its risks for the treatment of Wilson's disease. The Committee recommended that Wilzin be given marketing authorisation.

Other information about Wilzin:
The European Commission granted a marketing authorisation valid throughout the European Union for Wilzin to Orphan Europe SARL on 13 October 2004. The marketing authorisation was renewed on 13 October 2009.

The summary of opinion of the Committee for Orphan Medicinal Products for Wilzin is available here.
The full EPAR for Wilzin can be found here.

This summary was last updated in 10-2009.