IMPORTANT PRESCRIBING INFORMATION

October 29, 2020

Teva Administrative Offices:
Teva Pharmaceuticals USA, Inc.
Morris Corporate Center III
400 Interpace Parkway
Parsippany, NJ 07054

SUBJECT: Interruption in the Supply of GALZIN® (Zinc Acetate) Capsules

Dear Healthcare Professional:

We write to inform you of an interruption in the availability of GALZIN® (zinc acetate) 25 mg and 50 mg capsules in the United States market that will occur over the coming weeks and may extend until February 2021. As the only supplier of FDA-approved zinc acetate capsules in the United States for the treatment of Wilson's disease, Teva understands the critical role it plays in maintaining supply and is working diligently with the FDA to mitigate against the possibility of patients having no access to this medicine for any period of time.

To minimize or negate the impact to patients while GALZIN® is unavailable, Teva is exploring the possibility of supplying a very similar zinc acetate product of the same strength and dosage form manufactured in the United States for export to other markets. We will update you about our assessment of this option as soon as possible.

Teva provides this advance warning so that it may allow you time to make decisions about the immediate management of your patient(s) and commits to keeping you updated about all developments that may affect them. To that end, further communication will follow shortly.

If you have any questions about the information contained in this letter, please contact Teva US Medical Information via phone at 1-888-483-8279 or via email at USMedInfo@tevapharm.com.

Sincerely,

Denisa Hurtukova, MD
Vice President, Head of North America Medical Affairs
Teva Pharmaceuticals

Enclosure: [Full prescribing information for GALZIN® (zinc acetate) capsules]

INDICATION

GALZIN® (Zinc Acetate) therapy is indicated for maintenance treatment of patients with Wilson's disease who have been initially treated with a chelating agent, an agent that binds to copper. Wilson's disease results in a build–up of copper in the body.

IMPORTANT SAFETY INFORMATION

Do not use GALZIN if you are allergic to any of the ingredients in the product formulation.

GALZIN is not recommended for the initial treatment in patients with symptoms because of the delay in time it takes for zinc acetate to become effective in reducing copper levels. Patients who are having symptoms should be treated initially with copper binding agents (chelating agents).

GALZIN can cause stomach irritation. It may cause increases of liver and pancreatic enzymes that may last for weeks to months suggesting pancreatitis, an inflammation of the pancreas. The enzyme levels normally return to the high–normal range within the first one or two years of zinc therapy. There have been rare cases of death due to overdose of zinc acetate or with use of zinc acetate as initial treatment in patients with advanced liver disease.

Pregnancy Category: A. Studies in pregnant women have not shown that zinc acetate or zinc sulfate increases the risk of fetal abnormalities if taken during all trimesters of pregnancy. Zinc acetate should be used during pregnancy only if clearly needed. Zinc does appear in breast milk and zinc–induced copper deficiency in the nursing baby may occur. Therefore, it is not recommended to nurse while taking GALZIN. No patients below the age of 10 years have been studied.

Patients should take GALZIN on an empty stomach, at least one hour before or two to three hours after meals. Capsules should be swallowed whole, not opened or chewed. In the rare event of gastrointestinal intolerance, generally occurring with the morning dose, this dose may be taken between breakfast and lunch.

Patients must be monitored by their doctors to determine if the zinc acetate therapy is adequate. People with Wilson's disease should reduce their dietary copper intake. Patients must adhere strictly to their treatment regimen.

Please see the enclosed Prescribing Information.

Teva Pharmaceuticals
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