Taro Launches Specialty Generic Deferiprone Tablets, 500mg in the U.S.

September 28, 2020

HAWTHORNE, N.Y.--(BUSINESS WIRE)--Sep. 28, 2020-- Taro Pharmaceutical Industries Ltd. (NYSE: TARO) (“Taro” or “the Company”) today announced the launch of a new specialty generic, deferiprone, an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate. Deferiprone is the generic version of Ferriprox®. This product expands Taro’s capabilities to include specialty products.

Thalassemia syndromes are relatively rare in the United States, but are one of the most common autosomal recessive disorders in the world. The incidence of symptomatic cases is estimated to be approximately 1 in 100,000 individuals in the general population.[1]

At launch, Taro’s deferiprone tablets will be exclusively dispensed by BioPlus ® Specialty Pharmacy. For more information, visit Taro Cares at www.tarocares.com or call 1-888-292-0744.

Indication

Deferiprone is an iron chelator indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

Approval is based on a reduction in serum ferritin levels. There are no controlled trials demonstrating a direct treatment benefit, such as improvement in disease-related symptoms, functioning, or increased survival.

Limitations of Use: Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.

Important Safety Information

WARNING: AGRANULOCYTOSIS AND NEUTROPENIA

■ Deferiprone can cause agranulocytosis that can lead to serious infections and death. Neutropenia may precede the development of agranulocytosis.

■ Measure the absolute neutrophil count (ANC) before starting deferiprone and monitor the ANC weekly while on therapy.

■ Interrupt deferiprone if infection develops and monitor the ANC more frequently.

■ Advise patients taking deferiprone to report immediately any symptoms indicative of infection.

Deferiprone is contraindicated in patients with known hypersensitivity to deferiprone or to any of the excipients in the formulation.

Deferiprone can cause fetal harm. Women should be advised of the potential hazard to the fetus and to avoid pregnancy while on this drug. Advise females of reproductive potential to use an effective method of contraception during treatment with deferiprone and for at least six months after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment with deferiprone and for at least three months after the last dose. Advise females not to breastfeed during treatment with deferiprone and for at least 2 weeks after the last dose.

Avoid co-administration of deferiprone with other drugs known to be associated with neutropenia or agranulocytosis; however, if this is unavoidable, closely monitor the absolute neutrophil count. Avoid co-administration with UGT1A6 inhibitors. Allow at least a 4-hour interval between administration of deferiprone and drugs or supplements containing polyvalent cations (e.g., iron, aluminum, or zinc).

The most common adverse reactions are (incidence ≥5%) nausea, vomiting and abdominal pain, alanine aminotransferase increased, arthralgia, and neutropenia.

Inform patients that their urine might show a reddish/brown discoloration due to the excretion of iron. This is a very common sign of the desired effect, and it is not harmful.

Please see full Prescribing Information, including boxed WARNING and Medication Guide.

[1] Source: https://rarediseases.org/rare-diseases/thalassemia-major/#:~:text=Beta%20thalassemia%20is%20relatively%20rare,individuals%20in%20the%20general%20population

About Taro

Taro Pharmaceutical Industries Ltd. is a multinational, science-based pharmaceutical company, dedicated to meeting the needs of its customers through the discovery, development, manufacturing and marketing of the highest quality healthcare products. For further information on Taro Pharmaceutical Industries Ltd., please visit the Company’s website at www.taro.com.

Safe Harbor Statement

Certain statements in this release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements that do not describe historical facts or that refer or relate to events or circumstances the Company "estimates," "believes," or "expects" to happen or similar language, and statements. Although the Company believes the expectations reflected in such forward-looking statements to be based on reasonable assumptions, it can give no assurances that its expectations will be attained. Forward-looking statements are applicable only as of the date on which they are made.

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