FDA OKs first oral blood thinning medication for children

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(HealthDay)—The first oral blood thinning medication for children was

approved by the U.S. Food and Drug Administration, the agency announced Monday.

Pradaxa (dabigatran etexilate) oral pellets were approved to treat children ages 3 months to 12 years with venous thromboembolism (VTE) directly after treatment with an injectable blood thinner for at least five days. The tablets were also approved to prevent recurrent clots among children in this age group who have completed treatment for their first VTE. The capsule form of Pradaxa was also approved for these indications in patients ages 8 years and older.

The approval was based on safety and efficacy data from an open-label study of 267 pediatric patients who were randomly assigned to receive either Pradaxa or standard of care. The composite end point of no recurrence of blood clots, major and minor bleeding events, or death was met by 45.8 percent of patients randomly assigned to Pradaxa and 42.2 percent of patients who were randomly assigned to standard of care. Safety data were derived from an open-label, single-arm study of 214 patients with a history of blood clots. Recurrence of blood clots occurred in three patients (1.4 percent), which was comparable to that seen with standard of care.

The most commonly reported side effects of Pradaxa included digestive system symptoms and bleeding. The FDA notes the drug can also cause serious and fatal bleeding. It is not recommended for patients with bioprosthetic heart valves or triple-positive antiphospholipid syndrome. A boxed warning on the prescription label cautions that early treatment discontinuation could increase the risk for blood clots.

The approval was granted to Boehringer Ingelheim.

More information: More Information