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Promacta approval expanded to kids with rare blood disorder

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(HealthDay)—U.S. Food and Drug Administration approval of the drug Promacta (eltrombopag) has been expanded to include children one year and older with a rare blood disorder called chronic immune thrombocytopenic purpura (ITP).

ITP is characterized by a low blood platelet count. Promacta is now approved for the disorder among children who have had unsatisfactory results with other drugs, or with surgery to remove the spleen, the agency said in a news release.

Platelets help blood clot, and people with ITP can develop bleeding under the skin or in mucous membranes such as the mouth. Once-daily Promacta is designed to help increase platelet production, the FDA said.

The drug, available in pill or powder form, was clinically evaluated in a trial involving 159 people. Some 62 percent of those who took Promacta saw an improvement in platelet count, compared with 32 percent among people who took a placebo.

Promacta's most common side effects included upper respiratory infection, diarrhea, abdominal pain, rash and an increase in liver enzymes.

The drug has not been evaluated among children less than a year old, the FDA said.

Promacta is produced by Novartis, based in East Hanover, N.J.

More information: Visit the FDA to learn more.