Generic Name:
Eltrombopag
Trade Name:
Promacta
Company:
Novartis
Notes:

Novartis announced that FDA has expanded the approval of eltrombopag for first-line treatment of adults and pediatric patients aged 2 years and older with severe aplastic anemia (SAA) when the drug is taken in combination with standard immunosuppressive therapy.

SAA is a rare, life-threatening, acquired blood disorder in which a patient's bone marrow fails to produce enough red blood cells, white blood cells, and platelets. As a result, people living with this serious disease may experience debilitating symptoms and complications, such as fatigue, trouble breathing, recurring infections, and abnormal bruising or bleeding that can limit their daily activities.

Peltrombopag is an oral thrombopoietin receptor agonist that is already approved for SAA in patients who have had an insufficient response to IST. It is also approved for adults and children with chronic immune thrombocytopenia (ITP) who are refractory to other treatments, and for the treatment of thrombocytopenia in patients with chronic hepatitis C virus (HCV) infection.

In the clinical study upon which approval was based, the most common adverse reactions reported (incidence ?5%) were abnormal liver function tests, rash, and skin discoloration, including hyperpigmentation.

Medication Monitor Categories:
Supplemental Approvals