Novartis – Recall of Promacta® (eltrombopag)

- On May 12, 2019, the FDA announced a consumer-level recall of some lots of Novartis' Promacta (eltrombopag) oral suspension because of a risk of potential peanut flour contamination that occurred at a third-party contract manufacturing site.
    - Promacta 12.5 mg, 25 mg, 50 mg and 75 mg tablets are not impacted by this recall and are not manufactured in the same facility.
- The recalled products were distributed nationwide through specialty pharmacies and are listed below:

Product Description	NDC#	Lot# (Expiration Date)
Promacta 12.5 mg oral suspension	0078-0972-61 (carton); 0078-0972-19 (packet)	8H57901589 (09/2020); 9H57900189 (12/2020); 9H57900289 (12/2020)

- Promacta 12.5 mg for oral suspension is indicated for the treatment of certain adult and pediatric patients with chronic immune thrombocytopenia, certain adult patients with hepatitis C-associated thrombocytopenia, and certain adult and pediatric patients with severe aplastic anemia who have not received prior immunosuppressive therapy or had an insufficient response to immunosuppressive therapy. Refer to the Promacta drug label for full prescribing information.
- Peanut is a known food allergen. Potential cross contamination with peanut flour, even in small traces, can lead to hypersensitivity reaction in a population of patients with an unknown or known sensitivity to peanut antigen, including a medically significant anaphylactic reaction, which can be fatal.
- To date, Novartis has not received any reports or adverse events for this recall.
- Patients with the recalled product should stop taking their therapy and consult with their healthcare provider. Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Promacta.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- Patients that have impacted product should contact **1-866-918-8772** for return instructions. For more information regarding this recall, contact Novartis at **1-888-669-6682**.