

Promacta - (50 mg and 75 mg ; Tablets)

Generic Name	Eltrombopag Olamine	Innovator	Novartis
Dosage	50 mg and 75 mg ; Tablets	Branded US Sales	More Than \$1000 mn
Probable FTF	None	Known Para IV Filers	Less Than 5
Other ANDA developers	More Than 5	Tentative Approvals	None
Final Approvals	None	Generic Launches	None
Indication	PROMACTA is a thrombopoietin receptor agonist indicated: • for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. PROMACTA should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. • for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. PROMACTA should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. • in combination with standard immunosuppressive therapy for the firstline treatment of adult and pediatric patients 2 years and older with severe aplastic anemia. • for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.		
Complexities	Yes		

Chronology Of Events

Please Contact contact@researchdelta.com to get Detailed Information.

Executive Summary

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Promacta - (12.5 mg and 25 mg ; Tablets)

Generic Name	Eltrombopag Olamine	Innovator	Novartis
Dosage	12.5 mg and 25 mg ; Tablets	Branded US Sales	More Than \$1000 mn
Probable FTF	None	Known Para IV Filers	Less Than 5
Other ANDA developers	More Than 5	Tentative Approvals	None
Final Approvals	None	Generic Launches	None
Indication	PROMACTA is a thrombopoietin receptor agonist indicated: • for the treatment of thrombocytopenia in adult and pediatric patients 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. PROMACTA should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding. • for the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. PROMACTA should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy. • in combination with standard immunosuppressive therapy for the firstline treatment of adult and pediatric patients 2 years and older with severe aplastic anemia. • for the treatment of patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.		
Complexities	Yes		

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