Abbreviated Prescribing Information: For further prescribing information, please refer to the DOPTELET® Summary of Product Characteristics (SPC) before prescribing.

DOPTELET®: Each film-coated tablet contains avatrombopag maleate equivalent to 20 mg of avatrombopag.

Indications: DOPTELET® is indicated for the treatment of severe thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo an invasive procedure.

Dosage and Administration: The recommended daily dose of avatrombopag is based on the patient’s baseline platelet count. For platelet count <40x10^9/L use 60mg once-daily dose (three 20mg tablets) for 5 days; for platelet count ≥40 to <50x10^9/L use 40mg once-daily dose (two 20mg tablets) for 5 days. Doses should be taken orally with food. Dosing should begin 10 to 13 days prior to the planned procedure. The patient should undergo their procedure 5 to 8 days after the last dose of avatrombopag.

Contraindications: Hypersensitivity to avatrombopag or to any of the excipients.

Warnings and precautions: Thrombotic/thromboembolic events: Patients with chronic liver disease are known to be at increased risk for thromboembolic events. Portal vein thrombosis has been reported at an increased frequency in patients with chronic liver disease who had platelet counts >200x10^9/L receiving a thrombopoietin receptor agonist. Severe hepatic impairment: There is limited information on the use of avatrombopag in patients with severe hepatic impairment. Avatrombopag should only be used in such patients if the expected benefit outweighs the expected risks. Use in patients with chronic liver disease undergoing invasive procedures: The objective of treatment with Doptelet is to increase platelet counts. While the benefit-risk profile for procedures that were not specifically included in the clinical studies is likely to be comparable, the efficacy and safety of avatrombopag have not been established in major surgeries like laparotomy, thoracotomy, open-heart surgery, craniotomy or excision of organs.

Interactions: P-gp inhibitors: Concomitant use of avatrombopag with P-gp inhibitors resulted in alterations in exposure that were not clinically significant. No dose adjustment is recommended. CYP3A4/5 and CYP2C9 inhibitors: Concomitant use of avatrombopag with strong CYP3A4/5 or CYP2C9 inhibitors increases avatrombopag exposure which is not expected to have a clinically important effect on platelet counts due to the 5-day treatment duration, and no dose adjustment is recommended. These patients should be evaluated on day of procedure for unexpectedly high increase in platelet count. Strong CYP3A4/5 or CYP2C9 inducers: Concomitant use of strong CYP3A4/5 or CYP2C9 inducers reduces avatrombopag exposure and may result in a decreased effect on platelet counts; however, no dose adjustment is recommended.

Undesirable Effects: Portal vein thrombosis was reported in one patient (n = 1/430) in the clinical trials; this adverse reaction was assessed as associated to avatrombopag but non-serious. A common adverse reaction was fatigue; uncommon were anaemia, portal vein thrombosis, bone pain, myalgia and pyrexia.


Company Reference: PP-9595

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals are asked to report any suspected adverse reactions. Adverse events should be reported. Forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Swedish Orphan Biovitrum Ltd at drugsafety@sobi.com.