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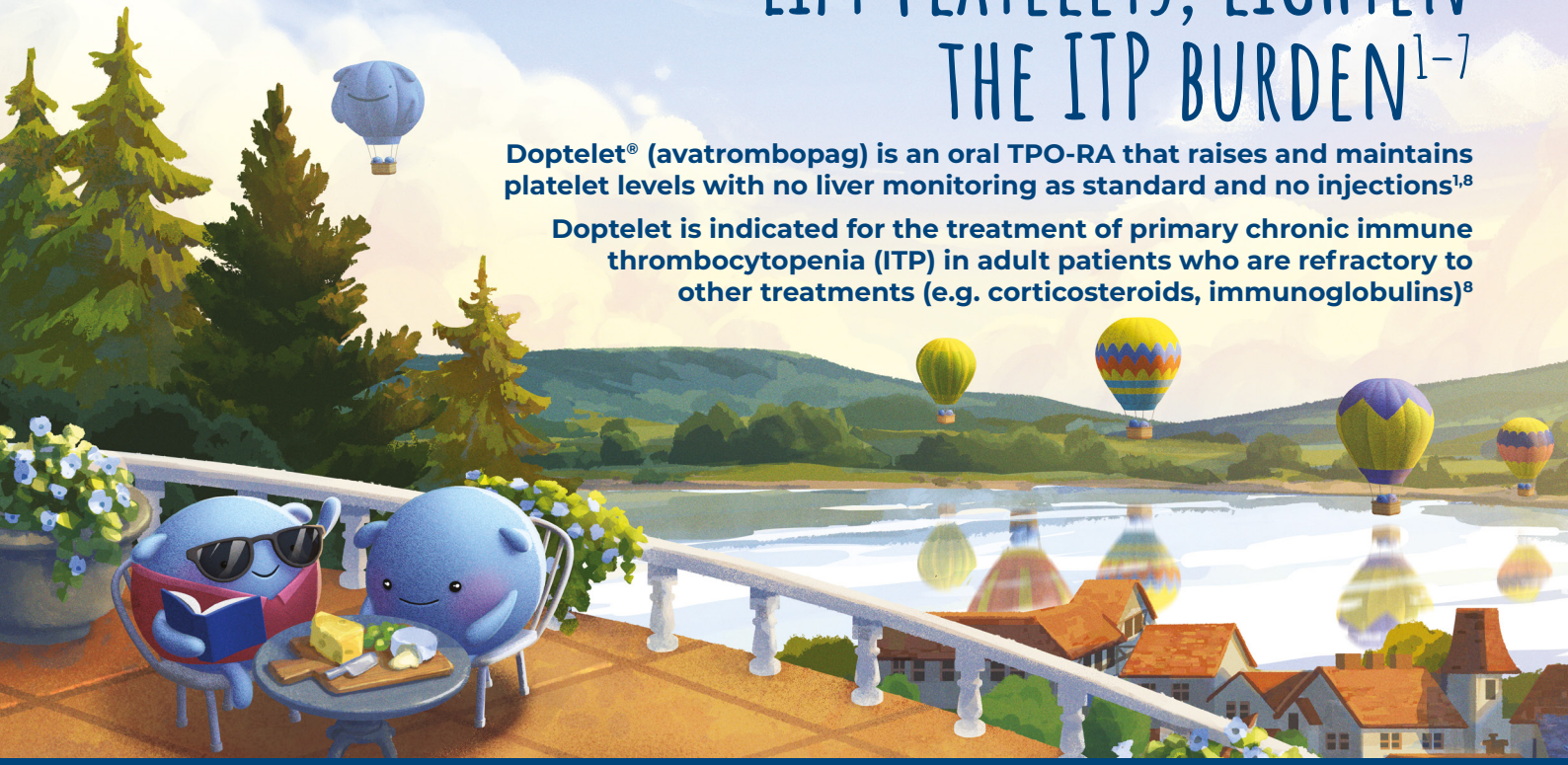
Doptelet®
(avatrombopag) tablets

LIFT PLATELETS, LIGHTEN THE ITP BURDEN[1–7]

Doptelet® (avatrombopag) is an oral TPO-RA that raises and maintains platelet levels with no liver monitoring as standard and no injections[1,8]

Doptelet is indicated for the treatment of primary chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments (e.g. corticosteroids, immunoglobulins)[8]



Adverse events should be reported. Reporting forms and information can be found at www.hpra.ie.
Adverse events should also be reported to Swedish Orphan Biovitrum Ltd at medical.info.uk@sobi.com or Telephone +44 (0) 800 111 4754.

Treatment should be initiated by and remain under the supervision of a physician who is experienced in the treatment of haematological diseases.[8]

This material is intended for healthcare professionals in the Republic of Ireland.

ITP, immune thrombocytopenia; TPO-RA, thrombopoietin receptor agonist.

Job code: PP-25496 **Date of preparation:** January 2025

Click here to visit the Doptelet HCP portal where you can access further information and resources

Doptelet helped patients get to the ≥50 × 10^9/L target within 8 days, and kept them there for months[1,2,8]

Doptelet was compared to placebo in a pivotal Phase 3 study*[1]

Rapid

Day 8

65.6% of Doptelet patients (n=21/32) achieved the platelet target of ≥50 × 10^9/L by Day 8 (secondary endpoint)†[1]

Sustained

12.4 weeks

median number of weeks Doptelet patients (n=32) were at or above the platelet target, without rescue therapy, during the 26-week study period (primary endpoint)**[1]

83.3%

of the time, patients on Doptelet (n=44) maintained their response in a post hoc analysis of the 6-month core and open-label extension study.‡[2] Loss of response was defined as platelet count <30 × 10^9/L for 2 consecutive appointments[2]

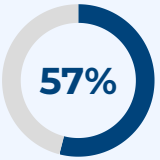
Doptelet SmPC recommends using the lowest dose of Doptelet needed to achieve and maintain a platelet count ≥50 x 10^9/L. Please refer to the SmPC for dose adjustment recommendations.[8]

Consistent

of Doptelet patients (n=44/47) achieved a response during the 6-month core and/or open-label extension study, in a post hoc analysis‡[2]

Doptelet may help to alleviate patients' treatment burden by reducing the need for concomitant steroids[4,9]

In a post hoc analysis of the Phase 3 study evaluating Doptelet vs placebo (N=49)[4]



of adult patients on corticosteroids (n=12/21) were able to discontinue them or reduce their dose after starting Doptelet[4]

*The efficacy and safety of Doptelet in adult patients with chronic primary ITP was evaluated in a Phase 3, multicentre, randomised double-blind, parallel-group, placebo-controlled study. The primary endpoint was cumulative number of weeks of platelet response, defined as platelet count ≥50 × 10^9/L in the absence of rescue therapy over 6 months of once-daily treatment.[1] †Vs 0.0% with placebo (n=0/17; p<0.0001).[1] **Vs 0.0 weeks with placebo (n=17; p<0.0001).[1] ‡In the combined core study and extension phase, the mean duration of exposure to Doptelet was 43.9 weeks, and the longest exposure to Doptelet was 75.7 weeks.[1]

ITP, immune thrombocytopenia; TPO-RA, thrombopoietin receptor agonist.

Doptelet absorption is not affected by food type or supplements[8]

Bioavailability and absorption <u>are unaffected</u> by the following food types and supplements:[4,8]

Dairy products

Calcium supplements or calcium-containing food

Iron supplements

Antacids

Doptelet is an oral TPO-RA that should be taken with food[8]

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Doptelet is consistently well tolerated in adult patients[1,8]

In the Phase 3 study of adult patients with primary chronic ITP (N=49), exposure-adjusted AEs were generally comparable to those of placebo*[1]

Any TEAE per patient-week

4.3% Doptelet (n=32)

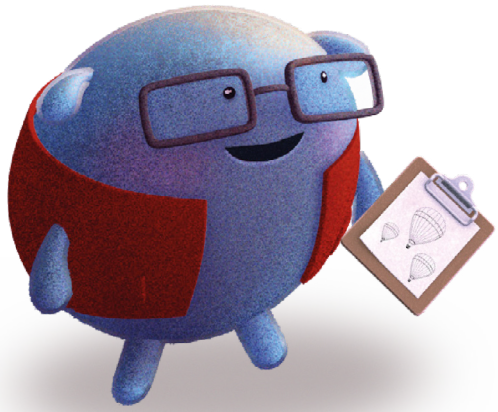
6.6% Placebo (n=17)

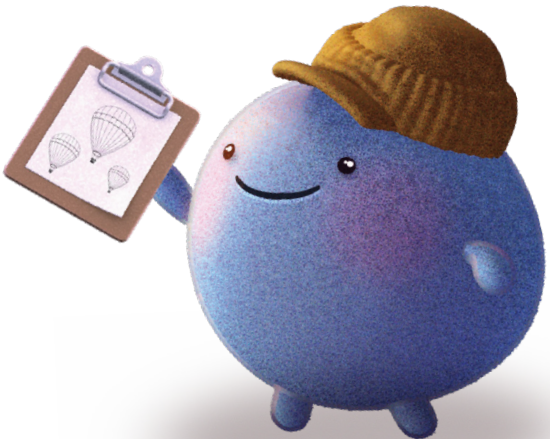
Any SAE per patient-week

1.2% Doptelet (n=32)

0.7% Placebo (n=17)

Mean duration of exposure: Doptelet 22.8 weeks vs placebo 8.9 weeks[1]





*Exposure-adjusted incidence rate = number of events/total patient-weeks exposure × 100%.[1]
AE, adverse event; ITP, immune thrombocytopenia; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

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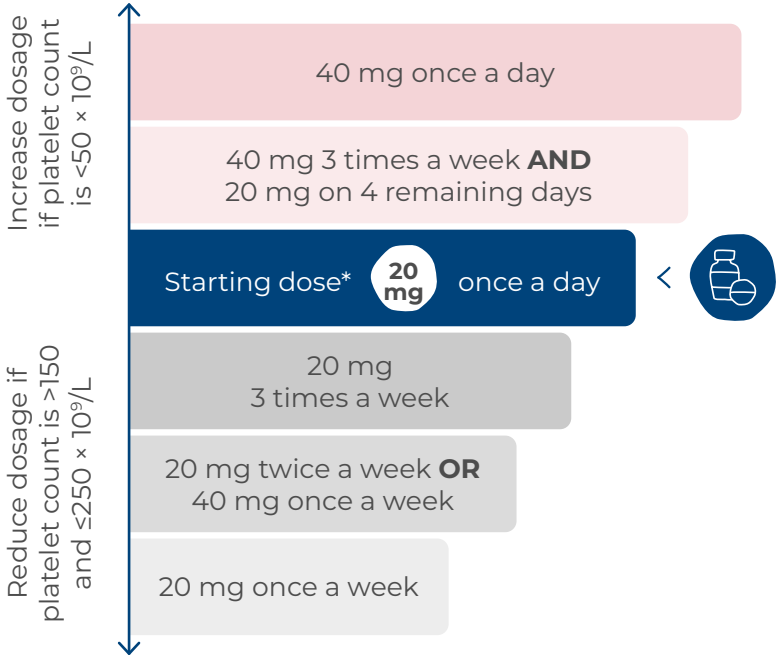
Most frequent TEAEs and SAEs during the 26-week Phase 3 core study[1]

	Core Study			
	Incidence n (%)		Exposure-Adjusted Incidence Rate %*	
	Placebo (n=17)	**Doptelet** (n=32)	**Placebo** (n=17)	**Doptelet** (n=32)
Any TEAE	**10 (58.8)**	**31 (96.9)**	**6.6**	**4.3**
Headache	2 (11.8)	12 (37.5)	1.3	1.6
Contusion	4 (23.5)	10 (31.3)	2.6	1.4
Upper respiratory tract infection	1 (5.9)	6 (18.8)	0.7	0.8
Arthralgia	0 (0)	4 (12.5)	0	0.5
Epistaxis	3 (17.6)	4 (12.5)	2.0	0.5
Fatigue	1 (5.9)	4 (12.5)	0.7	0.5
Gingival bleeding	0 (0)	4 (12.5)	0	0.5
Petechiae	1 (5.9)	4 (12.5)	0.7	0.5
Thrombocytopenia	0 (0)	2 (6.3)	0	0.3
Pharyngitis	1 (5.9)	0 (0)	0.7	0
Hypertension	1 (5.9)	2 (6.3)	0.7	0.3
Nasopharyngitis	0 (0)	3 (9.4)	0	0.4
Any SAE	**1 (5.9)**	**9 (28.1)**	**0.7**	**1.2**
Headache	0 (0)	2 (6.3)	0	0.3
Vomiting	0	2 (6.3)	0	0.3
Platelet count decreased	0	1 (3.1)	0	0.1

Doptelet provides simple dosing and flexible titration[8]

Start patients with a dosage strength of 20 mg once daily and adjust as needed*[8]



Use the lowest dose of Doptelet needed to achieve and maintain a platelet count of ≥50 × 10^9/L[8]

- After initiating therapy with Doptelet, assess platelet counts weekly until a stable platelet count of ≥50 × 10^9/L to ≤150 × 10^9/L has been achieved, and then obtain platelet counts monthly thereafter[8]
- If the platelet count is <50 × 10^9/L after 4 weeks of Doptelet 40 mg once a day, discontinue Doptelet[8]
- If the platelet count is >250 × 10^9/L after 2 weeks of Doptelet 20 mg weekly, discontinue Doptelet[8]
- Due to the potential risk of platelet counts above 400 × 10^9/L within the first few weeks of treatment, patients should be carefully monitored for any signs or symptoms of thrombocytosis[8]

Please refer to SmPC for complete dosing information[8]

*Initial dose regimen for all patients except those taking moderate or strong dual inducers or moderate or strong dual inhibitors of CYP2C9 and CYP3A4/5, or of CYP2C9 alone. This has been simplified; for more details refer to the SmPC.[8]

References

1. Jurczak W, et al. *Br J Haematol*. 2018;183(3):479–490.
2. Jain S, et al. *Platelets*. 2023;34(1):2195016.
3. McDonald V, et al. *Hematology*. 2021;26(1):799–808.
4. Al-Samkari H and Nagalla S. *Platelets*. 2022;33(2):257–264.
5. Tsykunova G and Ghanima W. *Ther Clin Risk Manag*. 2022;18:273–286.
6. Oladapo A, et al. *Ther Adv Hematol*. 2023;14:1–11.
7. Song A and Al-Samkari H. *Expert Review of Clin Immun*. 2022;18(8):783–791.
8. Doptelet European Union Summary of Product Characteristics. Available at: *https://www.ema.europa.eu/en/documents/product-information/doptelet-epar-product-information_en.pdf* (Accessed: January 2025).
9. Neunert C, et al. *Blood Adv*. 2019;3(23):3829–3866.

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