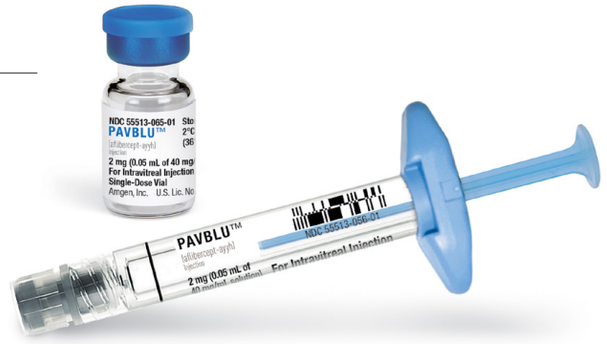
PAVBLU™ PRODUCT FACT SHEET



INDICATIONS

PAVBLU™ is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:

Neovascular (Wet) Age-Related Macular Degeneration (AMD)

Macular Edema Following Retinal Vein Occlusion (RVO)

Diabetic Macular Edema (DME)

Diabetic Retinopathy (DR)

PAVBLU™ is not indicated for Retinopathy of Prematurity, for which Regeneron has marketing exclusivity.

PRODUCT INFORMATION

NDC	Description	Quantity
55513-056-01	Blister pack containing 2 mg (0.05 mL of a 40-mg/mL solution) sterile, single-dose prefilled plastic syringe	One per carton
55513-065-01	Single-dose glass vial containing 2 mg (0.05 mL of a 40-mg/mL solution)	One per carton

STORAGE AND HANDLING REQUIREMENTS

Refrigerate PAVBLU™ at 2°C to 8°C (36°F to 46°F). PAVBLU™ may be kept at room temperature (up to 30°C (86°F)) for a single-period of 3 days. Do not freeze. Do not use beyond the date stamped on the carton and container label. Store in the original carton until time of use to protect from light. Do not open sealed blister tray until time of use.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

SUPPLIED AND MARKETED BY

Amgen USA Inc.

amgen.com

PAVBLU.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

PRODUCT INFORMATION

Medical Information: 800-77-AMGEN (800-772-6436)

REIMBURSEMENT INFORMATION

Amgen® SupportPlus: 866-264-2778 or www.AmgenSupportPlus.com

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- PAVBLU is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in PAVBLU.

Please see **full Important Safety Information** and click here for **full Prescribing Information**.

PAVBLU™ (aflibercept-ayyh)

PAVBLU™
(aflibercept-ayyh)

IMPORTANT SAFETY INFORMATION

INDICATIONS

PAVBLU™ (aflibercept-ayyh) is indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- PAVBLU is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to aflibercept or to any of the excipients in PAVBLU.

WARNINGS AND PRECAUTIONS

- Intravitreal injections, including those with aflibercept products, have been associated with endophthalmitis and retinal detachments and, more rarely, retinal vasculitis with or without occlusion. Proper aseptic injection technique must always be used when administering PAVBLU. Patients and/or caregivers should be instructed to report any signs and/or symptoms suggestive of endophthalmitis, retinal detachment, or retinal vasculitis without delay and should be managed appropriately.
- Acute increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including with aflibercept products. Sustained increases in intraocular pressure have also been reported after repeated intravitreal dosing with VEGF inhibitors. Intraocular pressure and the perfusion of the optic nerve head should be monitored and managed appropriately.
- There is a potential risk of arterial thromboembolic events (ATEs) following intravitreal use of VEGF inhibitors, including aflibercept products. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).
- The incidence of reported thromboembolic events in wet AMD studies during the first year was 1.8% (32 out of 1824) in the combined group of patients treated with aflibercept compared with 1.5% (9 out of 595) in patients treated with ranibizumab; through 96 weeks, the incidence was 3.3% (60 out of 1824) in the aflibercept group compared with 3.2% (19 out of 595) in the ranibizumab group. The incidence in the DME studies from baseline to week 52 was 3.3% (19 out of 578) in the combined group of patients treated with aflibercept compared with 2.8% (8 out of 287) in the control group; from baseline to week 100, the incidence was 6.4% (37 out of 578) in the combined group of patients treated with aflibercept compared with 4.2% (12 out of 287) in the control group. There were no reported thromboembolic events in the patients treated with aflibercept in the first six months of the RVO studies.

ADVERSE REACTIONS

- Serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections with aflibercept including endophthalmitis and retinal detachment.
- The most common adverse reactions (≥5%) reported in patients receiving aflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.
- Patients may experience temporary visual disturbances after an intravitreal injection with PAVBLU and the associated eye examinations. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

Click here for full Prescribing Information for PAVBLU.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please visit **PAVBLU.com** for additional information and resources.

Call **800-77-AMGEN (800-772-6436)** if you have questions about the preparation and administration of PAVBLU™.

Reference: PAVBLU™ (aflibercept) Prescribing Information. Amgen.

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