Ahzantive™ (aflibercept-mrbb) – New biosimilar approval

- On July 1, 2024, Formycon announced the FDA approval of Ahzantive (aflibercept-mrbb), biosimilar to Regeneron's Eylea (aflibercept).
    - Opuviz (aflibercept-yszy) and Yesafili (aflibercept-jbvf) were the first FDA-approved biosimilars to Eylea. Both were also approved as interchangeable to Eylea.
- Ahzantive, Opuviz, Yesafili and Eylea share the following indications for the treatment of:
    - Neovascular (wet) age-related macular degeneration (AMD)
    - Macular edema following retinal vein occlusion (RVO)
    - Diabetic macular edema (DME)
    - Diabetic retinopathy (DR).
- In addition, Eylea is also approved for the treatment of retinopathy of prematurity (ROP).
- Eylea is also available as Eylea HD indicated for AMD, DME, and DR.
- The approval of Ahzantive is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Eylea.
- Ahzantive is contraindicated in patients with ocular or periocular infections or active intraocular inflammation, and in patients with known hypersensitivity to aflibercept or any of the excipients in Ahzantive.
- Warnings and precautions for Ahzantive include endophthalmitis, retinal detachments, and retinal vasculitis with or without occlusion; increase in intraocular pressure; and thromboembolic events.
- The most common adverse reactions (≥ 5%) with Ahzantive use were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and increased intraocular pressure.
- The recommended dosage of Ahzantive for patients with AMD is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 12 weeks (3 months), followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months).
- The recommended dosage of Ahzantive for patients with RVO is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection once every 4 weeks (approximately every 25 days, monthly).
- The recommended dosage of Ahzantive for patients with DME or DR is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections, followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months).
- Refer to the Ahzantive drug labels for additional dosing details.
- Refer to the Eylea drug label for dosing for ROP.

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- Formycon/Coherus' launch plans for Ahzantive are pending. Ahzantive will be available as a 2 mg (0.05 mL of 40 mg/mL) solution in a single-dose vial.