FDA Approves Nufymco, Interchangeable Ranibizumab Biosimilar, for Retinal Diseases

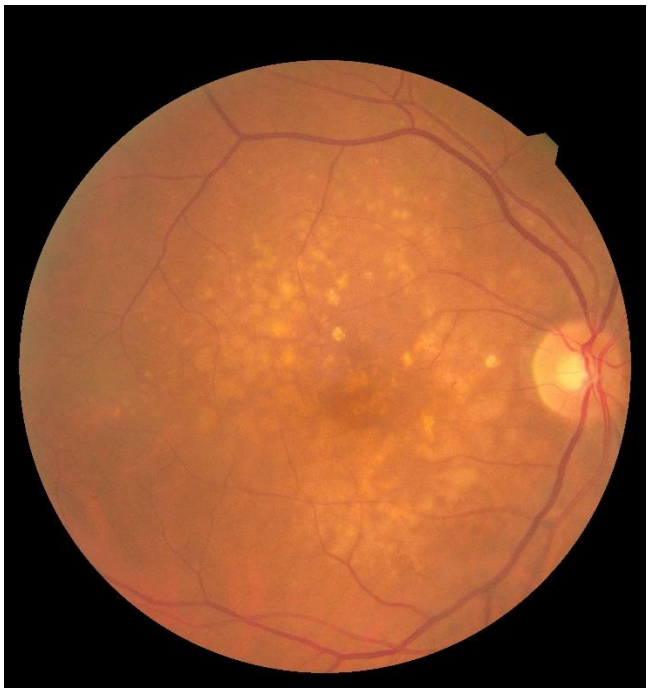
Key Takeaways

- Nufymco, a ranibizumab biosimilar, is FDA-approved for interchangeable use with Lucentis, expanding retinal disease treatment options.
- Biosimilars offer cost-effective alternatives to biologics, maintaining similar efficacy and safety profiles without clinically meaningful differences.
- Ranibizumab targets VEGF to manage retinal diseases but may cause adverse effects like ocular pressure increases and thromboembolic events.
- Nufymco is approved for wet AMD, diabetic retinopathy, and other conditions, available in 6-mg/mL and 10-mg/mL intravitreal injections.

Nufymco, the FDA-approved ranibizumab biosimilar, enhances treatment options for retinal diseases, improving patient access and affordability.

The FDA approved Nufymco (ranibizumab-leyk; Formycon AG, Zydus Lifesciences Ltd), an interchangeable ranibizumab biosimilar referencing Lucentis (Genentech, Novartis). According to a news release from the manufacturer, Nufymco can be used interchangeably in all Lucentis indications, expanding retinal therapeutic options and accessibility to patients who may have difficulty receiving or adhering to treatment.[1]

What are Biosimilars?



Biosimilars are biologic medications that are highly similar to biologics without having clinically meaningful differences from their reference products. They are often made with the same types of living sources and given to patients via the same mode of administration, have similar formulations and strengths, and have the same doses and treatment benefits while offering patients more affordable treatment options. Even though the active ingredients in generic drugs are often smaller, simpler, and easier to copy, biologics cannot be copied exactly.[2]

The biosimilar approval process is shorter because the treatment does not need to demonstrate superiority to its reference product but instead, biosimilarity or clinical similarity. Essentially, the goal of these trials is to identify that the investigational treatment is similar to its reference product, moves through patients similarly, and is produced and structured in a similar fashion.[2]

What Is Ranibizumab and What Is It Indicated for?

Reference ranibizumab is a humanized, recombinant monoclonal antibody fragment that targets vascular endothelial growth factor (VEGF) to manage and treat retinal diseases. This inhibits the interaction of VEGF-A—which plays a significant role in vascular leak and angiogenesis in the development of retinal diseases—with its receptors on endothelial cells, preventing endothelial proliferation, vascular permeability, and neovascularization. Additionally, reference ranibizumab has 1 binding site for VEGF, allowing 2 molecules of ranibizumab to bind to 1 VEGF dimer. The small size of ranibizumab allows for enhanced diffusion into the retina and choroid.[3]

Adverse effects (AEs) associated with ranibizumab use include conjunctival hemorrhage, eye pain, vitreous floaters, and both short- and long-term increases in ocular pressure. AEs specifically related to intravitreal injections include endophthalmitis, retinal detachments or hemorrhage, intraocular inflammation, and risk of thromboembolic events. Additionally, a few cases of the development of significant subretinal hemorrhage when administering intravitreal ranibizumab have also been reported. The overall risk of systemic AEs of ranibizumab is low; however, risks may increase in certain patients, especially in the elderly population. Ranibizumab is contraindicated for ocular or periocular infections and hypersensitivity, and it is recommended that those who have an ocular infection, recently underwent ocular surgery, or have increased intraocular pressures should avoid ranibizumab use.[3]

This action grants Nufymco interchangeability for Lucentis's FDA-approved indications, including the treatment of patients with age-related neovascular (wet) macular degeneration (AMD), diabetic macular edema (DME), diabetic retinopathy, macular edema due to retinal vein occlusion, and myopic choroidal neovascularization.1 Additionally, according to the FDA, Nufymco is available in 6-mg/mL and 10-mg/mL intravitreal injections.[4]

REFERENCES

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