23 April 2026
EMA/CHMP/91490/2026
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Rexatilux

ranibizumab

On 23 April 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rexatilux, intended for the treatment of neovascular (wet) age-related macular degeneration, visual impairment due to diabetic macular oedema, proliferative diabetic retinopathy, visual impairment due to macular oedema secondary to retinal vein occlusion and visual impairment due to choroidal neovascularisation.

The applicant for this medicinal product is Intas Third Party Sales 2005 S.L.

Rexatilux will be available as a 10 mg/ml solution for injection. The active substance of Rexatilux is ranibizumab, an antineovascularisation agent (ATC code: S01LA04). Ranibizumab is a monoclonal antibody fragment which modulates angiogenesis by inhibiting vascular endothelial growth factor A.

Rexatilux is a biosimilar medicinal product. It is highly similar to the reference product Lucentis (ranibizumab), which was authorised in the EU on 22/01/2007. Data show that Rexatilux has comparable quality, safety and efficacy to Lucentis. More information on biosimilar medicines can be found here.

The full indication is:

> Rexatilux is indicated in adults for:
>
> - The treatment of neovascular (wet) age-related macular degeneration (AMD)
> - The treatment of visual impairment due to diabetic macular oedema (DME)
> - The treatment of proliferative diabetic retinopathy (PDR)
> - The treatment of visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO)
> - The treatment of visual impairment due to choroidal neovascularisation (CNV).

Rexatilux must be administered by a qualified ophthalmologist experienced in intravitreal injections.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.