



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2025
EMADOC-1829012207-37184
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Ranluspec ranibizumab

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ranluspec, 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 Lupin Europe GmbH.

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

Ranluspec 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 Ranluspec has comparable quality, safety and efficacy to Lucentis. More information on biosimilar medicines can be found [here](#).

The full indication is:

Ranluspec 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).

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

Detailed recommendations for the use of this product will be described in the summary of product

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



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.