19 September 2019
EMA/CHMP/503493/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Lucentis

ranibizumab

On 19 September 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Lucentis. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted an extension to the existing indication to add the treatment of proliferative diabetic retinopathy (PDR).

For information, the full indication for Lucentis will be as follows:[2]

"Lucentis is indicated in adults for:

- The treatment of neovascular (wet) age-related macular degeneration (AMD)
- The treatment of visual impairment due to choroidal neovascularisation (CNV)
- 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)

Lucentis is indicated in preterm infants for:

- The treatment of retinopathy of prematurity (ROP) with zone I (stage 1+, 2+, 3 or 3+), zone II (stage 3+) or AP-ROP (aggressive posterior ROP) disease."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[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
[2] New text in bold

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