Genentech
A Member of the Roche Group

February 2024

Subject: LUCENTIS®(ranibizumab injection), New Warnings and Precautions: Retinal Vasculitis with or without Occlusion

Dear Health Care Provider:

The purpose of this letter is to inform you of the updated safety information for LUCENTIS. LUCENTIS is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- Diabetic Macular Edema (DME)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Retinopathy (DR)
- Myopic Choroidal Neovascularization (mCNV)

Risk of Retinal Vasculitis with or without Occlusion

An update to the Warnings and Precautions and Patient Counseling sections of the US Prescribing Information has been added. Retinal vasculitis with or without occlusion is a serious event that can cause permanent vision loss.

The benefit-risk profile of LUCENTIS for all its approved indications continues to be favorable.

Prescriber Action

- Counsel patients about the benefits and risks of LUCENTIS, including the risk of retinal vasculitis with or without retinal vascular occlusion.
- Patients treated with LUCENTIS should be instructed to report any changes in vision without delay to permit prompt and appropriate management [see Patient Counseling Information (17)]. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise the patient to seek immediate care from an ophthalmologist.
- LUCENTIS should be discontinued in patients who develop these events.
- Prescribers should refer to the Warnings and Precautions Section 5.5 of the US Prescribing Information.

Reporting Adverse Events and Company Contact

Health Care Providers should report any adverse events or product complaints suspected to be associated with the use of LUCENTIS to Genentech at 1-833-EYE-GENE. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Should you have any questions about the information in this letter or the safe and effective use of LUCENTIS, please contact us at: 1-833-EYE-GENE.This letter is not intended as a complete description of the benefits and risks related to the use of LUCENTIS. Please refer to the enclosed full prescribing information for additional information.

Sincerely,

Toby Patterson, MBBS
Senior Vice President
Head of U.S. Medical Affairs