Direct Healthcare Professional Communication

May 2023

Direct Healthcare Professional Communication for Lucentis® (Ranibizumab) 10 mg/ml solution for injection regarding "label containing information about the physical character (color of solution) that might be confusing"

Dear Healthcare Professional,

The General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

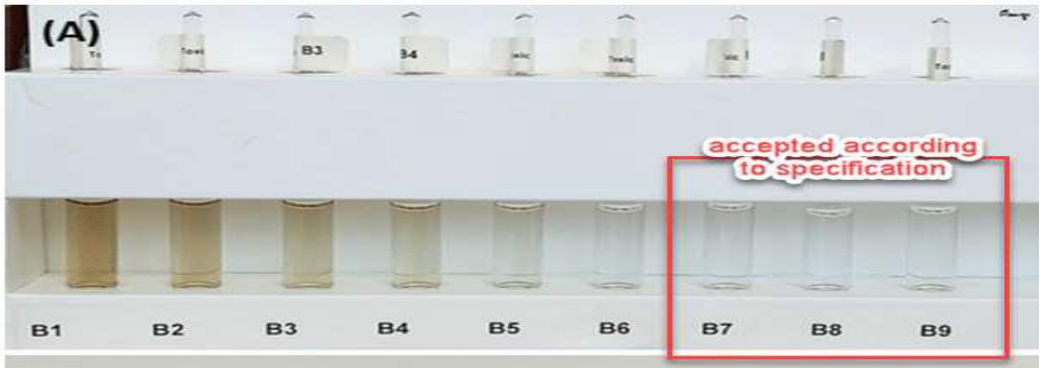
Summary:

- Novartis would like to inform you about Lucentis label containing information regarding the physical character of the product (color of solution) that might be confusing.

- The current DHPC letter is being circulated to Healthcare Professionals administering Lucentis in order to eliminate any confusion that possibly might be encountered due to the color description in the insert leaflet with revision date Feb 2022 used in production of some of the locally distributed Lucentis batches.

Further information on the color of solution:

- Novartis would like to confirm:
- That the pharmaceutical form description of Lucentis 10 mg/ml solution for injection is "sterile, clear, colorless to pale yellow" as per the latest approved label.
- However, as the accepted color of the solution lies also within the B7 to B9 (pale brown) scale, the leaflet was revised in Feb 2022 to address this color range.
- Please see for reference the color range for pale brown B7 to B9 in the below picture:



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- Instead of correctly "colorless to pale yellow to pale brown", the description of color solution was inadvertently changed to the shortened version of "colorless to pale yellow to brown".

- The leaflet with the revision date Feb 2022, including the potentially misleading color description "colorless to pale yellow to brown" was exceptionally approved for newly supplied batches till end of 2023.
- As it is likely not possible for human eyes to easily distinguish between pale yellow and pale brown, it is planned to simplify the description of color solution in the next update to "colorless to pale brownish-yellow" after granting needed approvals.

- Novartis assures you that there is no change to the product quality and safety.

- Most importantly, there has been no change in the positive benefit to risk assessment for Lucentis when used in accordance with the approved indications.

Further information
Lucentis is indicated for:

- The treatment of neovascular (wet) age-related macular degeneration (AMD)

- The treatment of visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM)

- The treatment of visual impairment due to diabetic macular edema (DME)

- The treatment of visual impairment due to macular edema secondary to retinal vein occlusion(branch RVO or central RVO)

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: General Administration for Pharmaceutical Vigilance

Email: pv.followup@edaegypt.gov.eg

Online reporting: https://primaryreporting.who-umc.org/EG
QR Code:

Hotline: 15301

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