NOVARTIS

No 31 / CIS, 26.01.2021

Dear healthcare professionals,

Novartis, in agreement with the Scientific Center of Drug and Medical Technology Expertise after Academician E. Gabrielyan wishes to provide information on ophthalmic products based on Safety Notice provided by Becton Dickinson Company.

It should be noted that Marketing Authorization is issued for the following medicinal products of Novartis (syringes, needles) listed by Becton Dickinson as well:

- Lucentis, (brolucizumab) solution for injection, N1 glass vial 0,23 ml and N1 filter needle (marketing authorization N 16590/1 issued 04 March 2019)

- VSIQQ (brolucizumab), solution for intraocular injection, 120 mg/ml, N1 glass vial and 1 filter needle (marketing authorization N 19953/1/1 issued 10 January 2022)

A brief summary presented below

Becton Dickinson has informed Novartis that the specifications of a few medical products have been updated and this update is not related to a new or serious technical or safety signal. The updated specifications contain information that these products are provided for intravitreal injection only.

There are no changes in the design, specifications, materials or manufacturing of Becton Dickinson products have been made.

In addition, the benefit-risk assessments for Lucentis®, VSIQQ® have been continuously evaluated and remain positive. These data support the continued use of the BD medical devices indicated in the BD Field Safety Notice for the preparation and administration of the Novartis

ophthalmic products according to the approved prescribing information and approved clinical trial protocols.

There is no need to implement any restriction or change to any of the listed medical products.

It is the responsibility of the drug manufacturer, in this case Novartis, to verify the compliance and validity of the syringes and needles for intraocular injection.

Novartis will promptly respond to any consumer inquiries on this issue by providing the information below (in case of inquiries).

Contact us for further questions. You may as well contact us at drugsafety.cis@novartis.com .

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online to the Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan of MoH of RA via www.pharm.am or call the hotline numbers: (+374 0) 20 05 05 and (+374 96) 22 05 05.

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