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Ranibizumab pre-filled syringe approved in the European Union: innovation to improve dose accuracy, reduce potential infection risk, and offer more efficient treatment administration

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Abstract

Purpose

Ready-to-use injections eliminate aseptic preparation steps, reducing potential iatrogenic eye infection risks due to suboptimal drug and device handling. Currently used pre-filled syringes (PFS) are unsuitable for intravitreal use as they are coated with a high amount of silicone (Si) oil, which over time may emulsify into the drug and upon injection may impact vision. The recently European Union (EU) approved ranibizumab (RBZ) PFS was specifically designed for single-use intraocular injection and may save physicians'/patients' time, improve dose accuracy, and help reduce eye infection risk

Methods

We describe some of the features, development process, and potential benefits of the RBZ PFS

Results

Design features of RBZ PFS (Figure) include: (i) a Luer-lock closure system that holds the needle tightly and enables a choice of needle; (ii) a small syringe barrel (0.5 mL) with low void volume, an unambiguous dose mark ensuring high dose accuracy, and non-reactive borosilicate glass for storage stability; (iii) a latex-free non-retractable plunger preventing inadvertent drawing of non-sterile air and thereby minimizing sterility-related ocular adverse events; (iv) an optimized siliconization process; and (v) a specially designed blister packaging preventing any contamination of sterile outer syringe surface. The development of minimally siliconized RBZ PFS used a 'baked silicone' process. Briefly, Si oil-in-water emulsion is spray coated to the barrel's inner surface and subsequently heat-fixed. Si oil migration into the RBZ solution was assessed using 2 orthogonal methods (inductively coupled plasma atomic emission spectroscopy and particulate matter analysis by microflow imaging), and was found to be minimal. No relevant differences in product stability between vials and syringes were observed (e.g. when assessed using cation exchange chromatography). The RBZ PFS is easy to hold and may increase the injection preparation efficiency by saving clinicians' time, compared to conventional vial use

Conclusions

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The RBZ PFS aims to improve overall efficiency of RBZ administration in clinical practice by potentially offering improved dose accuracy, a reduced risk of eye infection, and time savings for physicians and patients. RBZ PFS was approved for use in the EU in October 2013

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