

Summary details for EYLEA® (aflibercept) 8 mg Pre Filled Syringe 114.3 mg/ml - OcuClick®

<b>Name</b>	EYLEA® (aflibercept) 8 mg Pre Filled Syringe 114.3 mg/ml
<b>Composition</b>	1 ml solution for injection contains 114.3 mg aflibercept. Each pre-filled syringe contains 21 mg aflibercept in 0.184 ml solution. This provides a usable amount to deliver a single dose of 0.07 ml containing 8 mg aflibercept.
<b>Pharmaceutical form</b>	Solution for injection (injection) Clear to slightly opalescent, colourless to pale yellow, iso-osmotic solution, pH 5.8.
<b>Therapeutic indications</b>	Eylea is indicated in adults for the treatment of: <ul style="list-style-type: none"><li>▪ neovascular (wet) age-related macular degeneration (nAMD)</li><li>▪ visual impairment due to diabetic macular oedema (DMO)</li></ul>
<b>List of excipients</b>	Sucrose, Arginine hydrochloride, Histidine hydrochloride monohydrate, Histidine Polysorbate 20, Water for injections
<b>Shelf life</b>	2 years
<b>Storage</b>	<ul style="list-style-type: none"><li>▪ Store in a refrigerator (2 ° C – 8 ° C).</li><li>▪ Do not freeze.</li><li>▪ Keep the pre-filled syringe in its blister and in the outer carton in order to protect from light.</li><li>▪ Prior to usage, the unopened blister may be stored outside the refrigerator below 25 ° C for up to 24 hours.</li></ul>
<b>Nature and contents of container</b>	Pre-filled syringe (type I glass) with a grey plunger stopper (elastomeric rubber), a white Luer-lock adaptor with a grey tip cap (elastomeric rubber) and a blue OcuClick dosing system (PC/ABS plastic). Each pre-filled syringe contains 0.184 ml solution. Pack size of 1 pre-filled syringe.
<b>Pack dimensions</b>	70mm x 31mm x 137mm
<b>Special precautions for disposal and other handling</b>	The pre-filled syringe with OcuClick dosing system is for single use in one eye only. Extraction of multiple doses from a single pre-filled syringe with OcuClick dosing system may increase the risk of contamination and subsequent infection. Do not use if the package or its components are expired, damaged, or have been tampered with. Check the label on the pre-filled syringe with OcuClick dosing system to make sure you have the strength of Eylea that you intended to use. The 8 mg dose requires use of the Eylea 114.3 mg/ml pre-filled syringe. The intravitreal injection should be performed with a 30 G × ½ inch injection needle (not included). Use of a smaller size needle (higher gauge) than the recommended 30 G × ½ inch injection needle may result in increased injection forces. After opening the blister, proceed under aseptic conditions.
<b>NICE TA</b>	NICE ID NUMBER 10590 Covered by TA346 and TA294
<b>Licence number</b>	PLGB 00010/0758
<b>EAN</b>	5010605403897
<b>Bayer code</b>	90445760
<b>AMPP code</b>	43745011000001105
<b>DM &amp; D</b>	Eylea 21mg/184microlitres solution for injection pre-filled syringes
<b>NHS list price</b>	£998.00 (exc VAT)