

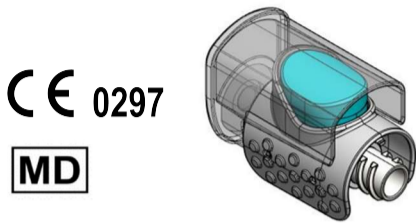
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Instructions for use

Picleo®

Paediatric Dosing Device for the administration of 10 µL nominal dose of Eylea® in pre-filled syringe in ROP.

REF 008.001.002



Picleo is compliant to the Regulation (EU) 2017/745 on Medical Devices (MDR).



Refer to instructions for use

IMPORTANT NOTICE

Before use of Picleo, instructions for use must be read. Please read carefully. Pay attention to all instructions, especially those regarding safety, and follow them at all times.

Introduction

Thank you for choosing our Picleo paediatric dosing device for use with the Eylea® 40 mg/mL pre-filled syringe and a 30G x ½" / 0.3 x 13 mm low dead space needle for injection (referred to needle throughout the document) only.

These instructions for use contain information about the intended purpose and proper use and of any precautions to be taken when using Picleo. You should read the instructions carefully even if you have used Picleo or similar devices before.


The Picleo paediatric dosing device is intended to deliver a single 10 µL nominal dose into one eye.

If you have any questions or need technical assistance for our paediatric dosing device Picleo contact the legal manufacturer.

These instructions for use are also available on the website of the legal manufacturer: <https://www.effectummedical.com/imprint/>

Safety instructions

The following warnings and symbols are used in these operating instructions or on the labeling:

 Caution: This notice indicates a potential hazard. Not following these instructions can result in injury.



Refer to the instructions for use



Authorized representative in the European Community



Do not reuse



Do not re-sterilize



Keep dry



Keep away from sunlight



Do not use if blister or packaging is damaged



Manufacturer



To be used by date



Catalogue number



Batch code (Lot number)



Medical device



Sterilized using irradiation



Single sterile barrier system



Single sterile barrier system with protective packaging outside



CE mark with identification of notified body



Unique Device Identifier



Translation



Importe

Notice to the User

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established. Manufacturer address

Effectum Medical AG

Kirchgasse 11

CH - 4600 Olten

Schweiz

Reuse of Picleo

Do not reuse the Picleo paediatric dosing device



Caution: After Picleo has been used once, it is no longer sterile, and is considered contaminated. Reuse/contamination may result in increased risk of intraocular infection. Also, the device will no longer accurately deliver the 10 µL nominal dose

Intended Use

Picleo paediatric dosing device is intended to facilitate the intravitreal administration of a single 10 µL nominal dose of Eylea® 40 mg/mL medicinal product in pre-filled syringe by delivering a fixed volume.

Indication and Patient Target Group

Picleo aids the intravitreal administration of the recommended dose of Eylea to the preterm infant with Retinopathy of Prematurity (ROP).

Contra-Indications

Do not use Picleo for the intravitreal administration of Eylea to patients other than preterm infants with Retinopathy of Prematurity (ROP). For contraindications of the medicinal product Eylea consult information provided with the medicinal product.

Performance Characteristics and clinical benefits

The intended use of the Picleo paediatric dosing device is to facilitate the intravitreal delivery of a single 10 µL nominal dose of Eylea medicinal product with a fixed volume. The delivered volume range is from 8 µL to 14 µL.

The clinical benefit of the paediatric dosing device is thus to deliver medicinal substances in a more precise way to the patient when compared to manual application.

The benefit of Picleo is the delivery of the therapeutic dose of Eylea in a more precise way when compared to manual application without the use of Picleo. For this, low dead space needles must be used and air bubbles must be removed from the system during priming as described under 'Preparation and handling'.



Caution: Presence of air bubbles can lead to underdosing.

Intended Users

The intended users of Picleo are physicians who are qualified to administer intravitreal medications to preterm infants, and those health care professionals who assist in the preparation of the injection.

Use Picleo only after training.

Combinations with Picleo paediatric dosing device

Picleo shall be used only with the Eylea® (aflibercept) 40 mg/mL solution for injection in pre-filled syringe (Bayer).

Picleo shall be used with low dead space injection needles only. The following low dead space injection needles are recommended:

TSK, 30G x ½" / 0.3 x 13 mm (Art. N. LDS-30013I-100)

OcuJect - OcuSafe®, 30G x ½" / 0.3 x 13 mm (Art. N. PN0403-03)

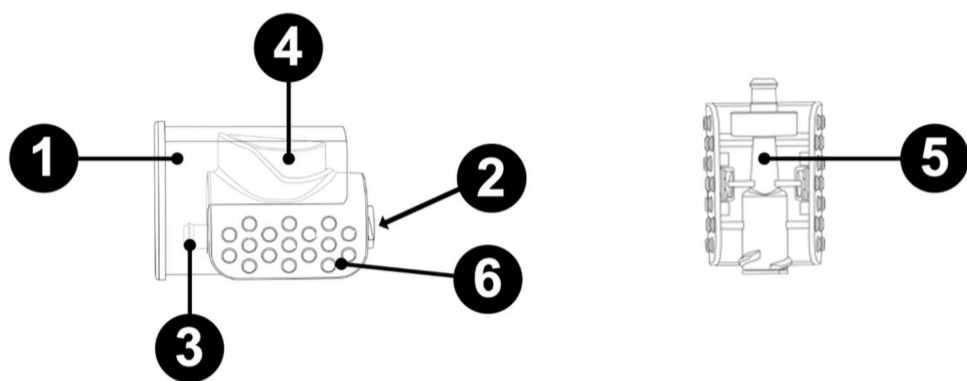


Any other combinations are not supported by the manufacturer.



Preparation and handling Picleo

Device description



1. Cover
2. Connection for the pre-filled syringe (female Luer Connector)
3. Connection for the needle (male Luer Connector)
4. Dose button
5. Viewing window
6. Grip area

Operating principle

Apply aseptic handling technique, assemble the Picleo paediatric dosing device between the pre-filled syringe and the injection needle. Depress the syringe plunger rod to eliminate air bubbles from the system and to fill the Picleo paediatric dosing device and the needle with medicinal product. It is not required to align the syringe plunger with the dosing line on the pre-filled syringe, because after air removal and priming, the Picleo paediatric dosing device and needle contain the required dose volume. Fully depress the dose button on the Picleo paediatric dosing device to deliver a single volume of 10 µL.

Important information

1. Use the Picleo paediatric dosing device only with the Eylea 40 mg/mL pre-filled syringe and a 30G 1/2" (0.3 x 13 mm) low dead space injection needle. Respective instructions must be followed. The Picleo paediatric dosing device is designed for use in combination with that pre-filled syringe and low dead space needle only.
2. The Picleo paediatric dosing device is provided sterile. Do not use if the packaging is damaged or has been tampered with.
3. Use aseptic technique when removing the Picleo paediatric dosing device from its blister pack and for all subsequent steps to prevent contamination.
4. Assemble pre-filled syringe and injection needle firmly to the Picleo paediatric dosing device to avoid leakage as well as accidental detachment.
5. Air bubbles must be removed from the system, and the system must be primed. It is not required to align the syringe plunger with the dosing line on the pre-filled syringe when using the Picleo paediatric dosing device.
6. Make sure not to touch the dose button of the Picleo paediatric dosing device before the medicinal product administration. Should the dose button be inadvertently depressed during assembly, do not proceed and discard the device and the pre-filled syringe. Select a new Picleo paediatric dosing device and follow assembly procedure steps using a new pre-filled syringe.
7. Medicinal product will remain in pre-filled syringe and Picleo paediatric dosing device after correct dose administration. Do not administer this residual solution but discard it.
8. The Picleo paediatric dosing device is for single use in one eye only. Never re-use the device as it will malfunction and contamination increases the risk of intraocular infection.

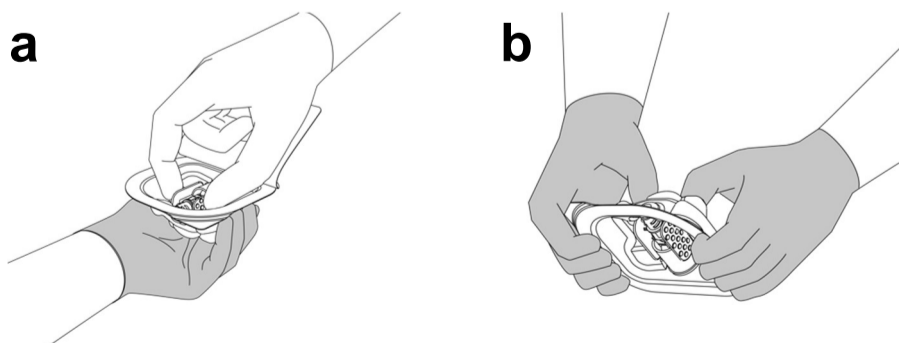
Storage

1. Keep within its original packaging.
2. Keep away from sunlight.
3. Do not open sealed blister pack before time of use.
4. Do not use beyond use by date.

Disposal

Dispose the Picleo paediatric dosing device as well as any unused medicinal product in accordance with local requirements.

1. When ready to administer Eylea, open the carton of the Picleo paediatric dosing device and remove the blister pack. Carefully peel open the blister pack. Using aseptic technique, carefully remove the Picleo paediatric dosing device from the blister pack either by taking it out of the blister pack (a) or pushing it out of the blister pack (b). Note: Darker gloves indicate contact to non-sterile surface.



! Caution: Only the inside of the blister pack and the enclosed Picleo paediatric dosing device are sterile. To avoid contamination do not touch the Luer Connectors.

2. Remove the syringe cap by holding the pre-filled syringe in one hand while using your other hand to grasp the syringe cap with the thumb and fore finger. Twist off (do not snap off) the syringe cap. Firmly twist the pre-filled syringe onto the female Luer Connector (see device description #2) of the Picleo paediatric dosing device.



3. Hold the Picleo paediatric dosing device at the grip area and carefully remove the cover from the Picleo paediatric dosing device by pulling it straight off.



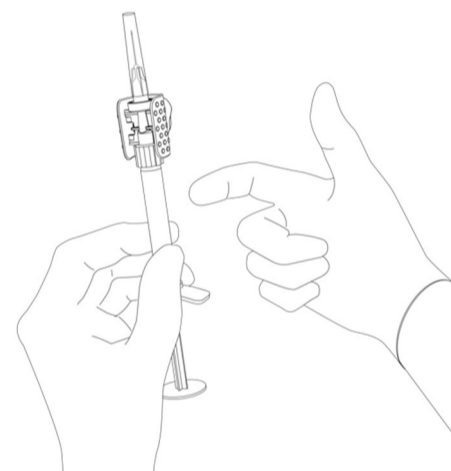
! Caution: To avoid incorrect dosing, do not touch the dose button.

4. Hold the Picleo paediatric dosing device at the grip area and firmly twist the 30G low dead space injection needle onto the male Luer Connector of the Picleo paediatric dosing device.



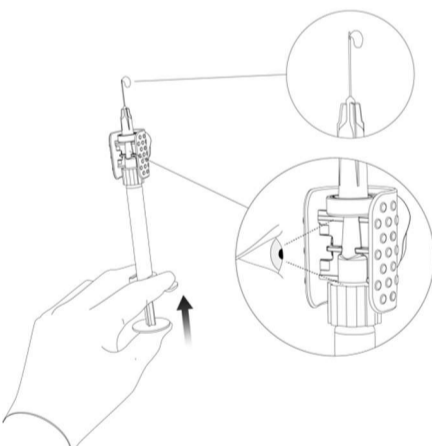
! Caution: Only use a low dead space injection needle. Using any other needle type can lead to underdosing. Pre-filled syringe and injection needle must be assembled firmly to the Picleo paediatric dosing device to avoid accidental detachment as well as leakage. Take care to not depress the syringe plunger rod while assembling.

5. Hold the pre-filled syringe with the injection needle pointing upwards and the viewing window of the Picleo paediatric dosing device facing towards you. Inspect the medicinal product and Picleo paediatric dosing device for particulates. Check the pre-filled syringe for air bubbles. If there are any air bubbles, gently tap the pre-filled syringe with your finger until the bubbles rise to the top.



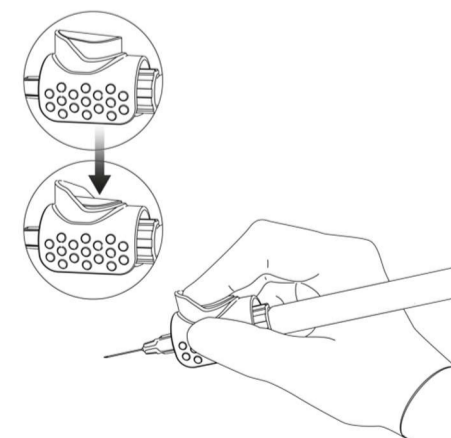
! Caution: Do not use the pre-filled syringe nor the Picleo paediatric dosing device if particulates are visible.

6. Remove the cap from the needle. Prime the system by slowly depressing the plunger rod while observing through the viewing window. Eliminate air bubbles from the pre-filled syringe and the Picleo paediatric dosing device. The system is now ready for intravitreal injection.



! Caution: Aligning the syringe plunger with the dosing line on the pre-filled syringe is not required. After air removal and priming, the Picleo paediatric dosing device and injection needle contain the required volume. To avoid compromising the sterility of the medicinal product, do not pull-back the plunger.

7. Hold the paediatric dosing device at the grip area. Insert the injection needle intravitreally following local guidelines for paediatric patients, ensuring proper injection technique. When ready, completely depress the dose button on the Picleo paediatric dosing device to administer the dose. You will hear a click once the dose button has been fully depressed. This confirms that the dose has been delivered correctly.







! Caution: Never administer the dose by depressing the syringe plunger rod as this may result in incorrect dosing. Because only the medicinal product within the needle and Picleo paediatric dosing device will be injected, residual medicinal product will remain in the



pre-filled syringe and the Picleo paediatric dosing device. Do not administer any residual medicinal product. The Picleo paediatric dosing device is for single use in one eye only. After injection any unused medicinal product must be discarded. Avoid the needle touching the lens and damaging it.



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YOUR START-UP TO MARKET

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	<p>EMERGO EUROPE Westervoortsedijk 60 NL-6827 AT Arnhem Nederland</p>
	<p><i>* Placeholder for UK Representative</i></p>
	<p>Bayer AG Kaiser-Wilhelm-Allee 1 DE-51373 Leverkusen Deutschland</p>
	<p>MediLingua Medical Translations BV Poortgebouw, Rijnsburgerweg 10 NL-2333 AA Leiden Nederland</p>

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