

## Aflibercept

40 mg/mL

Solution for injection

### Content for the Healthcare Professional Guide

Active substance(s) (INN or common name):	Aflibercept
Product(s) concerned (brand name(s)):	▼ Afqlir 40 mg/mL solution for injection in a pre-filled syringe; 40 mg/mL solution for injection in a vial
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This guide was prepared as an additional risk minimisation measure and fulfils the conditions of the marketing authorisation for aflibercept 40 mg/ml solution. This guide contains important information about this medicine and how to correctly administer it to your patients.

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Please also refer to the Summary of Product Characteristics (SmPC).

For safe use, please provide your patients with:

- the Patient Guide,
- the audio version of the Patient Guide. The link to the audio version of the Patient Guide is available on the website: [www.afliberceptrowex.eu](http://www.afliberceptrowex.eu)

Further information can be found in the SmPC and on the website of the marketing authorization holder (MAH): [www.afliberceptrowex.eu](http://www.afliberceptrowex.eu). The educational materials and product information for aflibercept 40 mg/ml are available on this site.

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## Summary of aflibercept, 40 mg/mL

Approved indications for adults	<ul style="list-style-type: none"><li>• Wet age-related macular degeneration (AMD)</li><li>• Diabetic macular oedema (DMO)</li><li>• Branch retinal vein occlusion (BRVO)</li><li>• Central retinal vein occlusion (CRVO)</li><li>• Myopic choroidal neovascularization (mCNV)</li></ul>
Dosage per injection	2 mg
Injection volume	0.05 mL
Administration form	Pre-filled syringe and vial

### Contraindications

- Hypersensitivity to aflibercept or any of the other ingredients listed in section 6.1 of the SmPC.
- Existing or suspected ocular or periocular infection.
- Existing severe intraocular inflammation.

### Important instructions for use

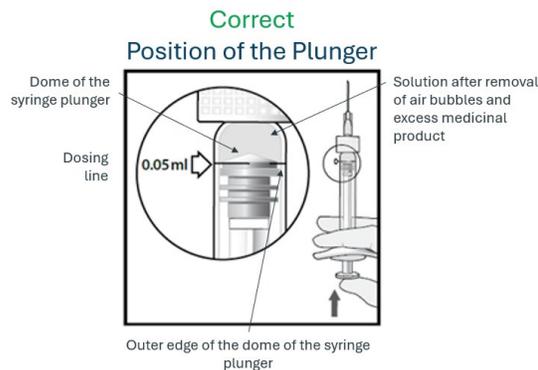
The vials of aflibercept 40 mg/mL solution for injection (2 mg dosage) as well as the pre-filled syringe of aflibercept 40 mg/mL solution for injection (2 mg dosage) contain more than the recommended dose of aflibercept. The entire volume must not be injected.

Adequate asepsis, including the use of a broad-spectrum microbicide, must be ensured to minimize the risk of intraocular infection.

A 30 G x ½ inch injection needle must be used for intravitreal injection.

Pre-filled syringe: Aflibercept 40 mg/mL solution for injection (2 mg dosage)

- Remove the excess amount and air bubbles from the pre-filled syringe and align the base (not the tip) of the dome-shaped plunger with the dosage line before injecting.
- When injecting, carefully press down the syringe plunger with constant pressure. Any remaining volume in the syringe must not be administered after the injection.



Special precautionary measures for storage and handling

Store in a refrigerator (2°C–8°C).

Aflibercept is not authorized for multiple withdrawals or injections, preparation of individual formulations, or splitting the contents of a pre-filled syringe/vial. The use of a single pre-filled syringe/vial for more than one injection may result in contamination and subsequent infection.

Special warnings and precautionary measures for use

In all cases, patients should be instructed to report any signs and symptoms of side effects immediately.

Side effect/risk	Risk minimization measures
Intraocular inflammation including endophthalmitis	Use adequate aseptic technique when preparing and performing the injection. Use recommended antiseptics. Monitor the patient after the injection.
Temporary increase in intraocular pressure	Fill the syringe properly, removing the excess amount and air bubbles from the syringe before use. Check the patient’s vision and intraocular pressure after the injection.
Medication errors	
Retinal pigment epithelial tear	Monitor the patient after injection.

Cataract	Measure for the correct injection site and apply the correct injection technique.
Off-label use/abuse	Use of the medicinal product only for treatment in the approved therapeutic indications and in the authorized dosage.
Embryo fetotoxicity	<ul style="list-style-type: none"><li>• Inform the patient about the use of a reliable contraceptive method during treatment for at least 3 months after the last intravitreal injection of aflibercept 40 mg/mL solution for injection in a pre-filled syringe/vial (2 mg dosage).</li><li>• Do not use aflibercept 40 mg/mL solution for injection in a pre-filled syringe/vial (2 mg dosage) during pregnancy unless the potential benefit outweighs the potential risk to the fetus.</li></ul>
Exposure during lactation	Aflibercept is not recommended during lactation.

### After the injection

Check the patient's vision immediately after the injection (hand movements or finger counting).

Immediately after intravitreal injection, patients should be monitored for an increase in intraocular pressure. After injection patients should be monitored for visual acuity.

Following an intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis immediately (e.g., eye pain, eye redness, photophobia, blurred vision).

### General information

The doctor is responsible for explaining the effects of anti-VEGF treatment to the patient. The Patient Guide is a tool to support patient communication about the disease and treatment. The Patient Guide is available from Sandoz on request. The doctor should make the Guide available to the patient. This is available both as a brochure and as an audio version. It contains information on signs and symptoms of side effects and circumstances in which a doctor should be consulted immediately.

The SmPC is a document that describes the properties of aflibercept and the approved indications. It is an important source of information for healthcare professionals on the safe and effective use of aflibercept. The SmPC is available via:

- the following link: [www.afliberceptrowex.eu](http://www.afliberceptrowex.eu)
- or [www.hpra.ie](http://www.hpra.ie)

Complete dosing information and recommendations can be found in the approved SmPC for aflibercept 40 mg/mL solution for injection in a pre-filled syringe/vial (2 mg dosage).

## Information on aflibercept, 40 mg/mL

Aflibercept is only to be used as an intravitreal injection and may only be administered by a qualified doctor who is experienced in performing intravitreal injections and is familiar with the use of the vial/pre-filled syringe.

Administration form	Pre-filled syringe and vial
Approved indications in adults 18 years and older	
• Neovascular (wet) AMD	Yes
• Visual impairment due to DMO	Yes
• Visual impairment due to macular oedema due to RVO, BRVO, or CRVO	Yes
• Visual impairment due to mCNV	Yes
Recommended dosage	2 mg
Injection volume	50 microliters or 0.05 mL
Dosage for approved therapeutic indications	<ul style="list-style-type: none"><li>• Dosing recommendations for wet AMD, RVO (BRVO and CRVO), DMO, and mCNV differ from each other.</li><li>• Complete dosage information can be found in the SmPC for aflibercept 40 mg/mL solution for injection in a pre-filled syringe/vial.</li></ul>

## Important information on the safety of aflibercept

### Contraindications

Aflibercept must not be used in the following cases:

- Hypersensitivity to the active substance aflibercept or any of the other ingredients listed in section 6.1 of the SmPC.
- Existing or suspected ocular or periocular infection.
- Existing severe intraocular inflammation.

### Special warnings and precautionary measures for use

#### Reactions caused by intravitreal injection

Intravitreal injections, including those with aflibercept, may lead to endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear, and iatrogenic traumatic cataract.

- Always use appropriate aseptic injection technique when administering aflibercept.
- Patients should be monitored after injections according to local practice recommendations to enable early treatment in the event of infection.
- Patients should be instructed to immediately report any signs and symptoms suggestive of endophthalmitis or any of the other side effects listed above.

The pre-filled syringe and the vial contain more than the recommended dose of 2 mg. The excess amount and the air bubbles must be removed from the syringe before injection.

- Inject the recommended dose.
- Any remaining residual solution must not be injected, as an increased injection volume can lead to a clinically relevant increase in intraocular pressure.

### Increase in intraocular pressure

A transient increase in intraocular pressure was observed within 60 minutes after intravitreal injections, including those with aflibercept.

- Monitor your patient after the injection procedure. Particular caution is required in patients with poorly controlled glaucoma (an injection with aflibercept should not be used in patients with an intraocular pressure  $\geq 30$  mmHg).
- Further instructions can be found in the section on post-operative aftercare following the injection.

### Immunogenicity

Aflibercept is a therapeutic protein, there is a possibility of immunogenicity.

- Patients should be instructed to report any signs or symptoms of intraocular inflammation (e.g., pain, photophobia, or redness) as these may be clinical signs of hypersensitivity.
- Further instructions can be found in the section on post-operative aftercare following the injection.

### Systemic effects

Systemic side effects including non-ocular hemorrhages and arterial thromboembolic events have been reported after intravitreal injection of VEGF inhibitors. There is a theoretical risk that these could be related to VEGF inhibition.

- There are limited data on safety in the treatment of patients with RVO (BRVO and CRVO), DMO or mCNV and wet AMD who have had a history of stroke or transient ischemic attack or myocardial infarction within the last 6 months. Caution should be exercised in the treatment of such patients.

### Special patient groups

Use in women of childbearing potential and during pregnancy

Reference is made to the following recommendations:

- Women of childbearing potential: Use reliable contraceptive methods during treatment and for at least 3 months after the last intravitreal injection of aflibercept 40 mg/mL solution for injection in a pre-filled syringe/vial (2 mg dosage).
- Pregnancy: Aflibercept 2 mg should not be used during pregnancy unless the expected benefit outweighs the potential risk to the fetus.
- Lactation: Very limited data in humans indicate that aflibercept may pass into breast milk in small amounts. Aflibercept is a large protein molecule and the amount of medicinal product absorbed by the infant is expected to be small. The effects of aflibercept on breastfed neonates/infants are not known. As a precautionary measure, breastfeeding is not recommended during the use of aflibercept.

### Post-operative aftercare

Immediately after the intravitreal injection:

- Check the patient's vision (hand movements or finger counting).
- Monitor patients for an increase in intraocular pressure. Appropriate monitoring may consist of checking the perfusion of the optic nerve head or tonometry. If necessary, sterile instruments should be available to perform a paracentesis.
- Instruct patients to immediately report any signs and symptoms suggestive of endophthalmitis (e.g., eye pain, eye redness, photophobia, blurred vision) without delay.

- Instruct patients to report any signs and symptoms that worsen over time after the injection.

### Side effects

Important signs and symptoms of side effects are:

Temporarily elevated intraocular pressure	Patients may experience changes in vision, such as temporary loss of vision, eye pain, light phenomena, redness of the eyes, nausea, and vomiting.
Retinal pigment epithelial tear	Patients may experience an acute deterioration in (central) vision, a blind spot (central scotoma), and distorted vision with deviation of vertical or horizontal lines (metamorphopsia).
Retinal tear or retinal detachment	Patients may experience sudden flashes of light, a sudden appearance or increase in vitreous opacities, a haze over part of the visual field, and changes in vision.
Intraocular inflammation including endophthalmitis	Patients may experience eye pain or increased discomfort, worsening redness of the eyes, photophobia or photosensitivity, swelling, and changes in vision, such as a sudden deterioration in vision or blurred vision.
Cataract (traumatic, nuclear, subcapsular, cortical) or lenticular opacities	Patients see lines and shapes, shadows and colors less clearly than before, and their vision changes.

See section 4.8 of the SmPC for the full list of possible side effects.

### Measures for the treatment of side effects

Make sure that an ophthalmologist is immediately available to your patients in the event of side effects.

Appropriate action and treatment of all side effects, including those related to intravitreal injection, should be in accordance with current clinical practice and/or standardized guidelines.

### Reporting of side effects

Reporting suspected side effects after authorization is very important. It allows continued monitoring of the risk-benefit ratio of the medicinal product.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events via HPRC Pharmacovigilance. Website: [www.hpra.ie](http://www.hpra.ie)

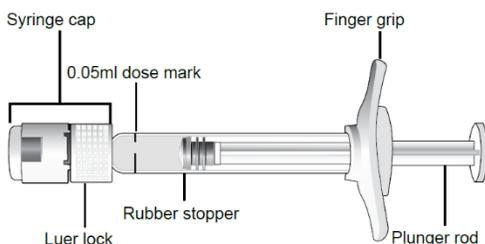
- or e-mail the MAH: e-mail: [adverse.event.ireland@sandoz.net](mailto:adverse.event.ireland@sandoz.net)

## Storage and use of aflibercept

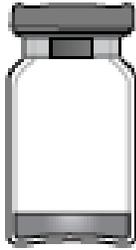
Aflibercept is a clear and colorless to slightly brownish-yellow solution.

The solution should be visually inspected for suspended solids and/or discoloration (the solution may be pale yellow, which is normal) or any change in appearance prior to use. The medicinal product must be discarded in each of these cases.

Do not use the contents of a vial/pre-filled syringe for more than one dose. Each vial/pre-filled syringe is intended for single use only. Multiple withdrawals from a single vial/pre-filled syringe may increase the risk of contamination and subsequent infection of the patient.



Each aflibercept 40 mg/mL solution for injection in a pre-filled syringe (2 mg dosage) contains more than the recommended 0.05 mL dose of aflibercept. The excess amount and all air bubbles in the syringe must be removed before the patient is injected with the recommended dose.



Each aflibercept 40 mg/mL solution for injection in a vial (2 mg dosage) contains more than the recommended 0.05 mL dose of aflibercept. The excess amount and all air bubbles in the disposable syringe must be removed before the patient is injected with the recommended dose.

Special precautionary measures for storage

	<p>Store AFQLIR in the refrigerator at 2°C - 8°C (36°F - 46°F); do not freeze. Keep the pre-filled syringe in the outer carton to protect from light.</p>
	<p>Prior to usage, the unopened blister of AFQLIR may be stored at room temperature below 30°C (below 86°F) for up to 14 days. After opening the blister, proceed under aseptic conditions.</p>
	<p>AFQLIR is a clear and colorless to slightly brownish-yellow solution.</p>
	<p>The solution should be inspected visually for any foreign particulates, cloudiness and/or discoloration or any variation in physical appearance prior to administration. In the event of either being observed, discard the medicinal product.</p> <p>Do not use if the packaging, or pre-filled syringe are damaged or expired.</p>

The inside of the sealed blister pack of aflibercept 40 mg/mL solution for injection in a pre-filled syringe (2 mg dosage) is sterile. Do not open the blister pack of the pre-filled syringe outside the operating theater.

After opening the blister pack or the vial, further handling must be carried out under aseptic conditions.

## Instructions for the use of aflibercept

### General preparation of the injection

Intravitreal injections must be performed by a qualified doctor who is experienced in performing intravitreal injections and familiar with the use of the vial/pre-filled syringe in accordance with medical standards and applicable guidelines.

Surgical hand disinfection, sterile gloves, a sterile drape, and a sterile eyelid retractor (or a comparable instrument) are recommended.

A 30 G x 1/2 inch injection needle must be used for intravitreal injections.

### Pre-filled syringe 40 mg/mL solution for injection (2 mg dosage)

Note: The aflibercept pre-filled syringe is a glass syringe with a rubber plunger, which requires a little more force to push in compared to plastic syringes (such as the vial). Familiarize yourself with this syringe before using it on a patient.

The pre-filled syringe and its contents must be checked before use. Do not use the pre-filled syringe if parts are damaged or loose. Do not use the pre-filled syringe if the syringe cap has become detached from the Luer lock. Look for particles and/or an unusual color or a changed appearance. If this is the case, discard the product.

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#### 1 Preparing the pre-filled syringe for use

It is important to prepare the pre-filled syringe using aseptic technique.

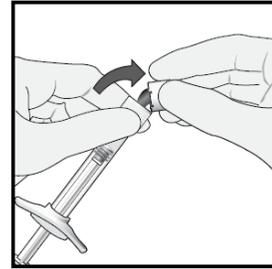
A surgical assistant should carry out the following steps: Remove the outer carton with the pre-filled syringe from the refrigerator, open it, and remove the blister pack with the syringe. The blister pack must not be placed on an aseptic surface, as the outer surface of the blister pack is not sterile. The inside of the blister pack and the pre-filled syringe are sterile. Carefully open the blister pack. After opening the blister pack, the aseptic technique must be used.

The qualified doctor performs the further steps including the use of sterile gloves (white gloves in the illustrations) when handling under sterile conditions: Remove the pre-filled syringe from the blister pack with two fingers, check the syringe visually and leave it in the sterile storage tray until further use.

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2 Removing the syringe cap

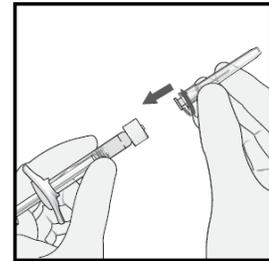
To remove the syringe cap, hold the syringe in one hand while using the other hand to grasp the syringe cap with the thumb and fore finger. Snap off (do not turn or twist) the syringe cap.



3 Note: To avoid compromising the sterility of the product, do not pull back on the plunger.

4 Attaching the needle

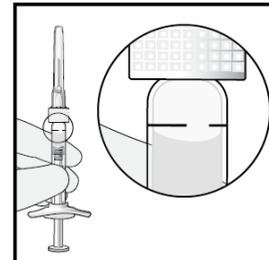
Using aseptic technique, firmly twist a 30G x ½ inch injection needle onto the Luer lock syringe tip.



5 Checking for air bubbles

Holding the syringe with the needle pointing up, check the syringe for bubbles.

If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.

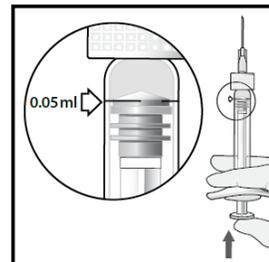


Carefully remove the needle cap by pulling it straight off.

6 Removal of air bubbles and excess medicinal product

Correct handling of the pre-filled syringe is important to avoid the risk of medication errors. To avoid overdosing, the excess quantity and the air bubbles must be removed.

Eliminate all bubbles and expel excess drug by slowly depressing the plunger rod to align the plunger dome edge with the black dosing line on the syringe (equivalent to 50 µL).



Note: Inject immediately after priming the syringe.

This glass syringe feels different to a conventional disposable plastic syringe.

After alignment with the dosing line, the remaining volume corresponds to the injection volume of 0.05 mL.

The exact positioning of the plunger is crucial. Incorrect positioning of the plunger can lead to the administration of a higher or lower dose than recommended.

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7 Aflibercept injection

Inject slowly until the rubber stopper reaches the end of the syringe to deliver the volume of 0.05 mL.

Confirm delivery of the full dose by checking that the rubber stopper has reached the end of the syringe barrel.

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8 The pre-filled syringe is for single use only.

Extraction of multiple doses from a pre-filled syringe may increase the risk of contamination and subsequent infection.

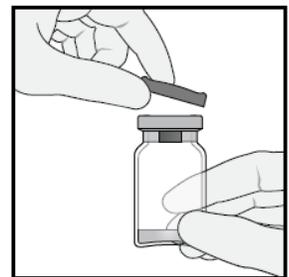
Any unused medicinal product or waste material must be disposed of in accordance with national requirements.

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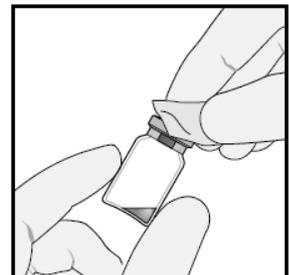
Vial 40 mg/mL solution for injection (2 mg dosage)

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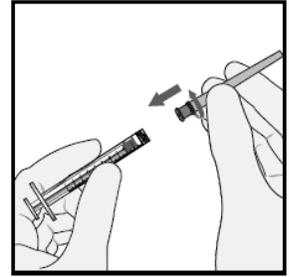
- 1 Remove the protective plastic cap from the vial.



- 2 Clean the top of the vial with an alcohol wipe.

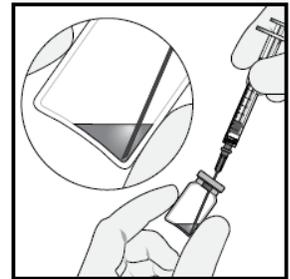


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- 3 Attach the 18 G x 1 and ½ inch, 5 micron filter needle to the sterile, Luer lock syringe.



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- 4 Push the filter needle into the center of the vial stopper until the needle is completely inserted into the vial and the tip touches the bottom or bottom edge of the vial.

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- 5 Using aseptic technique withdraw all the AFQLIR vial content into the syringe, keeping the vial in an upright position, slightly inclined to ease complete withdrawal. To deter the introduction of air, ensure the bevel of the filter needle is submerged into the liquid. Continue to tilt the vial during withdrawal keeping the bevel of the filter needle submerged in the liquid.



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- 6 Ensure that the plunger rod is drawn sufficiently back when emptying the vial to completely empty the filter needle.

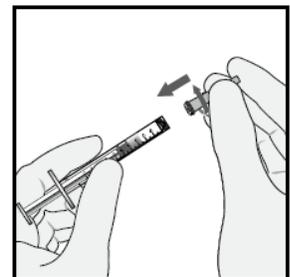
- 
- 7 Remove the filter needle from the syringe and properly dispose of the filter needle.

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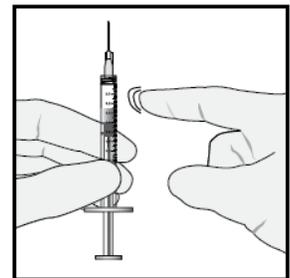
Note: The filter needle is not to be used for intravitreal injection.

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- 8 Attach the 30 G x ½ inch injection needle to the syringe by firmly twisting the injection needle onto the Luer lock syringe tip.

Carefully remove the needle cap by pulling it straight off.

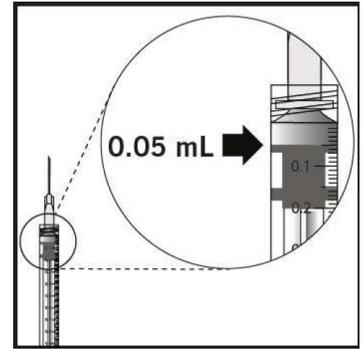


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- 9 Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.



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- 10 To eliminate all of the bubbles and to expel excess drug, slowly depress the plunger so that the plunger tip aligns with the line that marks 0.05 mL on the syringe.

Note: Inject immediately after preparation



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- 11 Inject slowly until the rubber stopper reaches the end of the syringe to deliver the volume of 0.05 mL. Confirm delivery of the full dose by checking that the rubber stopper has reached the end of the syringe barrel.

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- 12 The vial is for single use only. Extraction of multiple doses from a single vial may increase the risk of contamination and subsequent infection.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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### Intravitreal injection

- 
- 1 Apply topical anesthetic.



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- 2 Apply disinfectant (e.g., 5% povidone-iodine solution or equivalent) to the eyelid and eyelid margins and instill into the conjunctival sac. The disinfectant should remain on the surface for as long as recommended in local practice guidelines.



It is not necessary to dilate the pupil before the injection procedure.

- 3 Apply disinfectant (e.g., 10% povidone-iodine solution or equivalent) to the periocular skin, eyelids and eyelashes without exerting too much pressure on the eyelid glands. The disinfectant should remain on the surface for as long as recommended in the local practice guidelines.



- 4 Cover the face with a sterile drape and insert a sterile eyelid retractor. The conjunctival sac can be treated a second time with a disinfectant, e.g., a 5% povidone-iodine solution. The disinfectant should remain on the surface for as long as recommended in local practice guidelines.



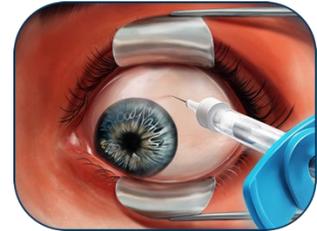
- 5 Ask the patient to look away from the injection site.

Position the eye accordingly. Mark an injection site in an area 3.5 to 4.0 mm posterior to the limbus.



- 6 Insert the injection needle into the vitreous cavity, avoiding the horizontal meridian and aiming towards the center of the globe.

Carefully inject the recommended dose with constant pressure on the plunger. No additional pressure should be applied once the plunger has reached the bottom of the syringe. Any residual solution in the syringe must not be administered after the injection.



Subsequent injections should not be made at the same scleral injection site.

