

OPUVIZ ▼ PRESCRIBER GUIDE

This Guide provides important information on OPUVIZ™ 40mg/mL solution for injection (2mg aflibercept dose), the medication itself, and how to correctly administer it to your patients.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspect adverse reactions.

Please provide the adult patient with the OPUVIZ patient guide, including its audio version (read out of the patient guide). The above information is available on www.sb-armm.eu/ie.

For further information and additional details on aflibercept, please see the Summary of Product Characteristics (SmPC), <http://www.ema.europa.eu>.

This Prescriber guide fulfils the conditions of the marketing authorisation and has been approved by HPRA

Version 1.0 approved by the HPRA (Jul 2026)



Intravitreal Injection Procedure Video

Please scan:



Or visit:

<https://www.sb-armm.eu/ie>

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KEY SUMMARY FOR AFLIBERCEPT USE IN ADULTS

Aflibercept is available in 40mg/ml solution for injection (2mg dose):

	Aflibercept 40mg/ml
Approved indication in adults	• Neovascular (wet) age related macular degeneration (AMD) • Visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO or central RVO) • Visual impairment due to diabetic macular oedema (DME) • Visual impairment due to myopic choroidal neovascularisation (myopic CNV)
Dose per injection	2mg
Injection volume	0.05ml
Presentation	vial and pre-filled syringe

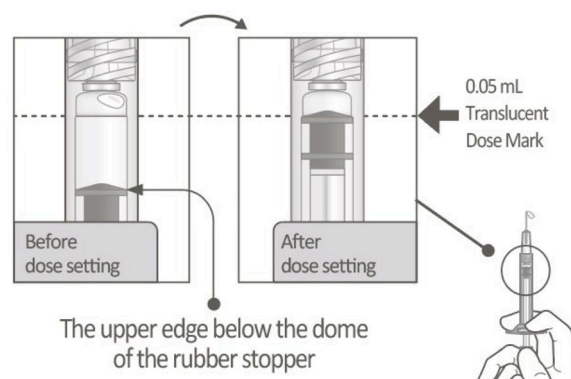
Contraindications

- Hypersensitivity to the active substance aflibercept or to any of the excipients listed in section 6.1 of the SmPC
- Active or suspected ocular or periocular infection
- Active severe intraocular inflammation

Key instructions for use in adults

- Each vial/pre-filled syringe is for single use only.
- The vials and the pre-filled syringe come with excess volume. Before injecting, syringes with solution withdrawn from the vial and the pre-filled syringes must be primed to the correct volume for injection according to the steps in the instructions for use.
- Ensure proper aseptic technique including the use of broad-spectrum microbicide to minimise risk of intraocular infection
- For the intravitreal injection, a **30 G x 1/2 inch injection needle** should be used. Use of a smaller size injection needle (higher gauge) than the 30G x 1/2 inch needle may result in increased injection forces.

- OPUVIZ 40mg/ml pre-filled syringe (2mg dose):
 - To expel the air bubbles along with excess medicinal product, slowly depress the plunger rod to align the upper edge below the dome (NOT the tip) of the rubber stopper with the translucent dose mark on the syringe (equivalent to 0.05 mL i.e. 2 mg aflibercept)
 - You may feel resistance when the rubber stopper contacts the dose mark. The resistance indicates the correct dosing volume of OPUVIZ has been reached.



Selected instructions for storage and handling of aflibercept

- **Store aflibercept in the refrigerator (2°C to 8°C)**
- **Prior to use, the unopened aflibercept 40mg/ml vials and pre-filled syringes may be kept in their cartons at room temperature up to 30°C for a period of up to 3 days.**
- Aflibercept is **not licensed for multi-dose**, further compounding or vial splitting. Extraction of multiple doses from a from a single vial **can lead** to contamination and subsequent infection

GENERAL INFORMATION

You must explain to the patient the implications of anti-VEGF treatment. The patient guide is a tool that will help you to communicate to your adult patient about the disease and treatment. This guide is available upon request to Samsung Bioepis, and you should distribute it to your adult patients. It is available as a booklet and as an audio guide option for your adult patients. It contains information on the signs and symptoms of adverse reactions and when they should seek medical attention.

To order additional copies of the aflibercept patient guide and/or the prescriber guide, please contact Samsung Bioepis at sb.armm@samsung.com.

The patient guide and its audio version are also available on <https://www.sb-armm.eu/ie>.

Please bring this to the patient's attention, for ease of access.

IMPORTANT SAFETY INFORMATION ABOUT AFLIBERCEPT

Special warnings and precautions for use

Intravitreal injection-related reactions

Intravitreal injections, including those with aflibercept, have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract.

- **Always use proper aseptic injection techniques** when administering aflibercept
- **Monitor patients following injections as per local practice** to permit early treatment if an infection occurs
- **Instruct patients to immediately report any signs and symptoms** suggestive of endophthalmitis or any of the adverse reactions mentioned below
- Refer to the post injection care section for further instructions

Increase in intraocular pressure

Transient increases in intraocular pressure have been seen within 60 minutes of intravitreal injection, including injections with aflibercept.

- Monitor the patient after the injection procedure and take special precaution in patients with poorly controlled glaucoma. Do not inject aflibercept while the intraocular pressure is ≥ 30 mm Hg. Both the intraocular pressure and perfusion status of the optic nerve head must be monitored and managed appropriately.
- Refer to the post-injection care section for further instructions

In all cases, instruct patients to immediately report signs and symptoms of adverse events

Adverse event/risk	Measures to minimize risk
Intraocular inflammation including endophthalmitis	Use proper aseptic technique when preparing the injection and during the injection itself Use recommended antiseptic agents Monitor patient after the injection
Transient Intraocular pressure (IOP) increase	Properly prime the syringe by removing excess volume and air bubbles from the syringe before administration Monitor patient's vision and IOP after the injection
Medication error	Check the carton and the label on the medication to ensure you have the correct dose of aflibercept
Retinal pigment epithelial (RPE) tear	Review pigment epithelial detachment (PED) features for risk of RPE tears. Monitor patient after the injection for symptoms such as acute decrease in (central) vision, blind spot (central scotoma), and distorted vision with deviation of either vertical or horizontal lines (metamorphopsia).
Cataract	Measure for correct site for the injection, use correct injection technique
Off-label use/misuse	Use medication only for treatment of approved indications, and use approved dose There is no relevant use of aflibercept in the paediatric population for the indications of AMD, CRVO, BRVO, DME and myopic CNV.
Embryo-foetotoxicity	Instruct women of childbearing potential to use effective contraception during treatment for at least 3 months after last injection Aflibercept should not be used during pregnancy unless the potential benefit outweighs the potential risk to the foetus
Exposure during breast-feeding	Aflibercept is not recommended in patients who are breast-feeding

Adverse drug reactions

See section 4.8 of the respective SmPCs for full list of potential adverse reactions and their frequency categories.

Key signs and symptoms of intravitreal injection-related adverse reactions include:

Adverse Drug Reaction	Key signs and symptoms
Transient increased intraocular pressure	Patients may experience vision changes such as temporary vision loss, eye pain, halos around lights, red eye, nausea and vomiting.
Tear of the retinal pigment epithelium	Patients may experience acute decrease in (central) vision, blind spot (central scotoma), and distorted vision with deviation of either vertical or horizontal lines (metamorphopsia)
Tear or detachment of the retina	Patients may experience sudden flashes of light, a sudden appearance or an increase of the number of vitreous floaters, a curtain over a portion of their visual field and vision changes.
Intraocular inflammation including endophthalmitis	Patients may experience eye pain or increased discomfort, worsening eye redness, photophobia or sensitivity to light, swelling, and vision changes, such as a sudden decrease in vision or blurring of vision.
Cataract (traumatic, nuclear, subcapsular, cortical) or lenticular opacities	Patients may experience less vivid lines and shapes, shadows and colour vision than before, and vision changes.

See section 4.8 of the SmPC for the full list of potential adverse reactions.

Post-injection care

- Evaluate vision immediately after injection (hand movement or finger counting)
- Monitor the patient for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or conducting a tonometry test. Sterile equipment for paracentesis should be readily available if anterior chamber paracentesis needs to be done.
- Instruct the patient to report any signs and symptoms suggestive of endophthalmitis (e.g. eye pain, redness of the eye, photophobia, blurring of vision) without delay
- Instruct the patient to report any signs or symptoms after the injection that get worse overtime

Management of adverse reactions

In case of any adverse reactions that concern your patient, they must have immediate access to an ophthalmologist.

Appropriate management of ALL adverse reactions, including those associated with the intravitreal injection, should be carried out according to clinical practice and/or following standardised guidelines.

Healthcare Professionals are asked to report any suspected adverse reactions. See section “Reporting suspected adverse reactions” in page 18 of this prescriber guide for how to report suspected adverse reactions.

Risk of medication error

Expel the excess volume, to avoid overdosing, and air bubbles from the syringe prior to injection.

Pregnancy and breast-feeding

The following recommendations are made

- **Women of childbearing potential**
Use effective contraception during treatment and for at least 3 months after the last intravitreal injection of aflibercept 40 mg/ml (2 mg dose).
- **Pregnancy**
There are no data on the use of aflibercept in pregnant women. Studies in animals have shown embryo-foetal toxicity.
Aflibercept 2 mg **should not be used during pregnancy** unless the potential benefit outweighs the potential risk to the foetus.
- **Breast-feeding**
Based on very limited human data, aflibercept may be excreted in human milk at low levels. Aflibercept is a large protein molecule and the amount of medication absorbed by the infant is expected to be minimal. The effects of aflibercept on a breast-fed newborn/infant is unknown. As a precautionary measure, breast-feeding is not recommended during the use of aflibercept.

STORAGE AND HANDLING OF AFLIBERCEPT

The aflibercept 40 mg/ml (2 mg dose) solution is clear and colourless to pale yellow. It is an iso-osmotic solution.

Inspect the solution visually before use, for any foreign particulate matter and/or unusual colour (the solution can be pale yellow, which is normal) **or any variation in physical appearance. If any of these are observed, do not use the product.**

Inspect the pre-filled syringe. If any part is damaged or loose, or if the syringe cap is not fully closed, do not use.

Do not split a vial/pre-filled syringe into more than one dose. Each vial is for single use in one eye only. Extraction of multiple doses from a single vial may increase the risk of contamination and subsequent infection in the patient.

Aflibercept 40mg/ml pre-filled syringe and vial for use

Aflibercept 40mg/ml pre-filled syringe

Each aflibercept 40 mg/ml solution for injection in a pre-filled syringe (2 mg dose) contains more than the recommended 0.05 ml dose of aflibercept.

Correct handling of the pre-filled syringe is important in order to avoid the risk of medication errors. This includes removal of the excess volume (to avoid overdosing) and air bubbles from the syringe, prior to injection.

Aflibercept 40mg/ml vial

Each aflibercept 40 mg/ml solution for injection in a vial (2 mg dose) **contains more than the recommended 0.05 mL dose of aflibercept.**

Correct handling of the filled syringe is important in order to avoid the risk of medication errors. This includes removal of the excess volume (to avoid overdosing) and air bubbles from the disposable syringe, prior to injection.

Special precautions for storage

- Store in a refrigerator (2°C to 8°C)
- Prior to use, unopened aflibercept 40mg/ml vials and pre-filled syringe blisters may be kept in their cartons at room temperature up to 30°C for a period of up to 3 days
- Do not freeze
- Keep the pre-filled syringe in its blister and in the outer carton in order to protect it from light. Keep the vial in the outer carton in order to protect from light

The inside of the sealed pre-filled syringe blister packaging, and the pre-filled syringe itself are sterile. Do not open the pre-filled syringe blister outside the clean administration room.

After opening the blister or vial, proceed under aseptic conditions.

INSTRUCTIONS FOR USE OF AFLIBERCEPT

General preparation for Injection

- Intravitreal injections must be carried out according to medical standards and applicable guidelines by **a qualified physician experienced in administering intravitreal injections and familiar with the handling** of the vial.
- Surgical hand disinfection, aseptic gloves, a sterile drape and a sterilised eyelid speculum (or equivalent) are recommended
- For the intravitreal injection, a 30 G x ½ inch injection needle should be used. Use of a smaller size injection needle (higher gauge) than the 30G x 1/2 inch needle may result in increased injection forces.

Pre-filled syringe 40mg/ml (2mg dose), solution for injection

Note: Become familiarised with how to use this syringe before using it on patients. The pre-filled syringe contains more volume than the recommended dose (0.05 mL), a part of the volume contained in the syringe has to be discarded prior to the administration.

1. Prepare the pre-filled syringe for administration

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

An assistant should carry out the following steps:

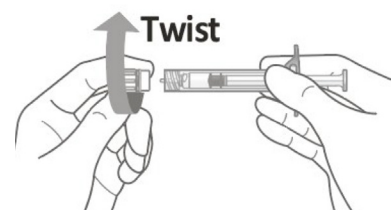
- Remove the carton containing the pre-filled syringe from the refrigerator.
- Open the carton and remove the blister containing the syringe.
- The blister must not be placed on an aseptic surface because the outside surface of the blister is not sterile. The inside of the sealed blister and the pre-filled syringe are sterile.
- Carefully peel open the blister. **Aseptic technique must be used once the blister is opened.**

The qualified physician carries out the remainder of the steps with sterile technique including the use of aseptic gloves (white gloves in pictures) when handling:

- With two fingers, remove the pre-filled syringe from the blister.
- Visually inspect the syringe.
- Place the syringe in a sterile tray until ready for assembly.
- Using aseptic technique, the injector should remove the syringe from the sterilised blister.

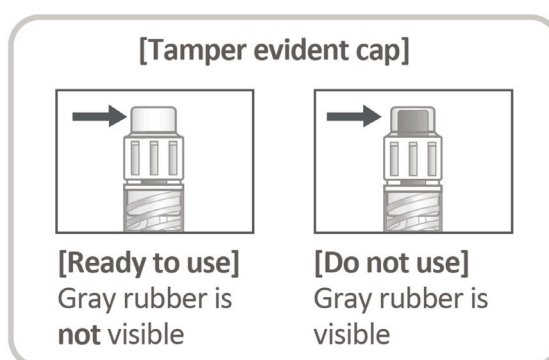
2. Remove the syringe cap

To remove the syringe cap, twist off (do not pull or snap off) the syringe cap by holding the syringe in one hand and the syringe cap with the thumb and forefinger of the other hand



Do not use the pre-filled syringe if:

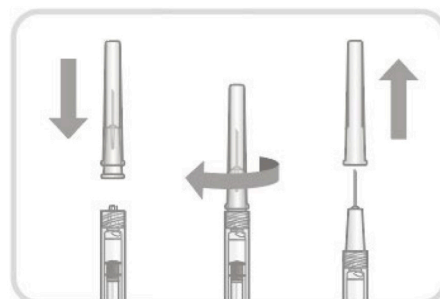
- particulates, cloudiness, or discoloration are visible.
- the syringe is damaged.
- the syringe cap is not fully closed.
- the gray rubber is visible in the transparent part of the syringe cap when holding the syringe vertically at eye level, indicating that the syringe has been tampered with.



3. Attach the needle

Using aseptic technique, attach a 30 G x ½ inch sterile injection needle firmly onto the syringe by screwing it tightly onto the Luer lock.

- Carefully remove the needle cap by pulling it straight off, when you are ready to administer Opuviz.
Note: Do not wipe the needle at any time.

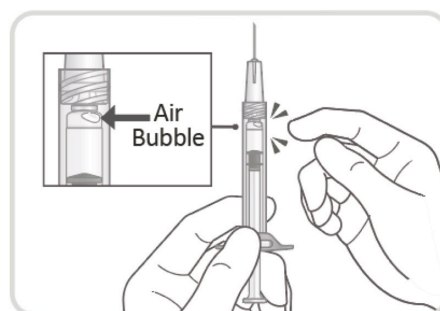


4. Check for bubbles

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.

5. To avoid compromising the sterility of the product, do not pull back on the plunger

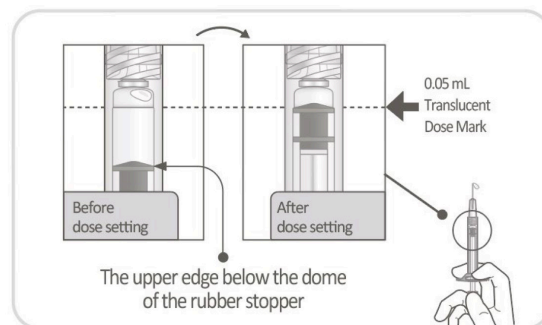


6. Eliminate air bubbles and excess drug

Correct handling of the pre-filled syringe is important in order to avoid the risk of medication errors. This includes removal of the excess volume (to avoid overdosing) and air bubbles.

The excess volume and air bubbles must be discarded prior to administration.

- Hold the syringe at eye level.
- Look closely and locate the translucent dose mark.
- Carefully push the plunger rod until the upper edge below the dome of the rubber stopper is aligned with the 0.05 mL translucent dose mark.
- You may feel resistance when the rubber stopper contacts the dose mark. The resistance indicates the correct dosing volume of Opuviz has been reached.



7. Inject aflibercept

The injection procedure should be carried out under aseptic conditions. Insert the needle into the injection site. Inject slowly until rubber stopper reaches the bottom of the syringe to deliver the volume of 0.05 mL.

Note: After injection, do not recap the needle or detach it from the syringe. This could lead to a needle stick injury.

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

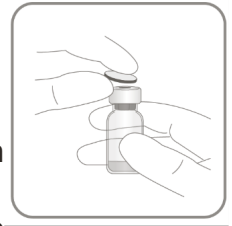
Dispose of any unused medicinal product or waste material in accordance with local regulations.

Vial 40 mg/ml (2 mg dose) solution for injection

1. Inspect the vial, and remove the vial cap

It is important to prepare the syringe with aflibercept from the vial, using aseptic technique. An assistant should carry out the following steps:

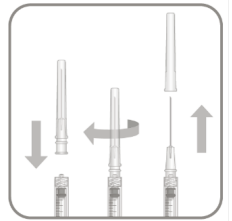
- Remove the carton containing the vial from the refrigerator. Let the carton and its contents reach room temperature.
- Open the carton, and remove the vial and place it upright on a flat surface to allow the solution to accumulate at the bottom of the vial.
- The vial should not be placed on an aseptic surface because the outside surface of the vial is not sterile. The inside of the vial is sterile.
- Check that the liquid is at the bottom of the vial.
- Visually inspect the vial and contents (the liquid).
- Remove the plastic cap and disinfect the outer part of the rubber vial stopper.



2. Attach the filter needle

The qualified physician should carry out the remaining steps using aseptic technique, including the use of aseptic gloves:

Using aseptic technique, screw on the 18 G x 1 ½ inch, 5-micron filter needle supplied in the carton to a 1 mL sterile Luer-lock syringe



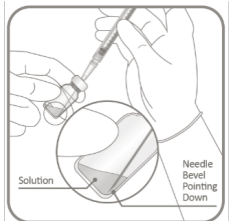
3. Insert needle into vial

Insert the filter needle into the centre of the vial stopper until the needle is completely inserted into the vial and the needle tip touches the bottom or bottom edge of the vial.



4. Draw up the solution

- Withdraw all of the aflibercept vial contents slowly into the syringe, keeping the vial in an upright position, slightly inclined to ease complete withdrawal.
- To avoid the introduction of air, ensure the bevel of the filter needle is submerged in the liquid.
- Continue to tilt the vial while withdrawing to allow the liquid to collect to the corner of the vial, keeping the bevel of the filter needle submerged in the liquid.
- Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle.



5. Remove the filter needle

Unscrew and properly dispose of the filter needle. Do not use the filter needle for intravitreal injection.

6. Attach the injection needle

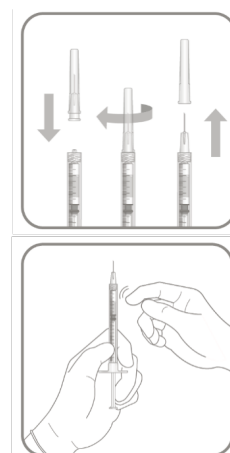
Using aseptic technique, firmly twist a 30G x ½ inch injection needle to the Luer-lock syringe tip. Use of a smaller size injection needle (higher gauge) than the 30G x ½ inch needle may result in increased injection forces.

7. Check for air bubbles

Holding the syringe with the needle pointing upwards, visually inspect the contents of the syringe. Check the solution for bubbles. If bubbles are present, gently tap the syringe with your finger until the bubbles rise to the top.

8. Eliminate air bubbles and excess drug

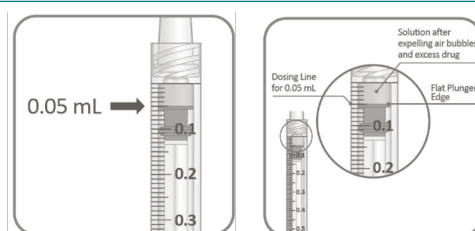
Correct handling of the filled syringe is important in order to avoid the risk of medication errors. This includes removal of the excess volume (to avoid overdosing) and air bubbles.



Aflibercept 2mg dose

Use 0.05 ml volume of aflibercept 40 mg/ml solution

Eliminate all air bubbles and expel excess drug by slowly depressing the plunger rod to align the flat plunger edge with the 0.05 ml line on the syringe for the aflibercept 40 mg/ml vial.



Attention! The aflibercept 2 mg dose uses 0.05 ml volume of Aflibercept 40 mg/ml solution. Accurate positioning of the plunger shown in the diagrams above is critical. Incorrect plunger positioning can lead to delivering more or less than the recommended dose.

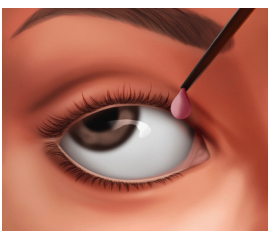
9. Each vial is for single use only. Dispose of any unused medicinal product or waste material in accordance with local regulations.

INJECTION PROCEDURE

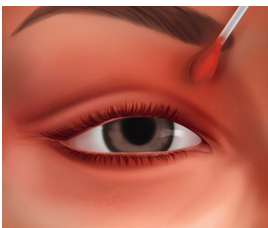
For further information on intravitreal injection procedure, sterile techniques (including periocular and ocular disinfection) and anaesthesia, please refer to local and/or national clinical guidelines.



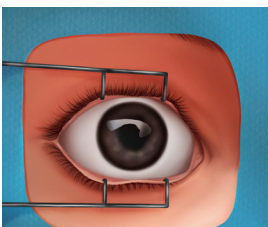
1. Administer topical anaesthesia. Eye dilation prior to the injection procedure is **not** necessary



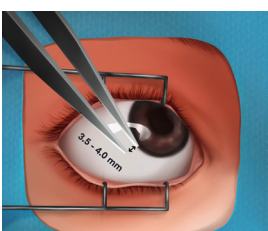
2. Apply disinfectant (e.g. 5% povidone iodine solution or equivalent) according to manufacturer's guidance. The disinfectant should be on the surface for at least 30 seconds



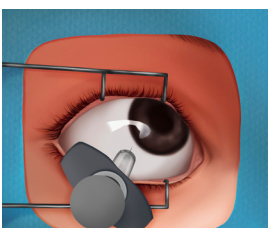
3. A disinfectant (e.g. 10% povidone iodine solution or equivalent) should also be applied to the periocular skin, eyelids, and eyelashes, avoiding extensive pressure to the periocular glands. The disinfectant should be on the surface for at least 30 seconds



4. Cover with sterile drape and insert sterile lid speculum. A second application of disinfectant, e.g., 5% povidone iodine solution, may be made to the conjunctival sac. Disinfectant should be on the surface for at least 30 seconds



5. Tell your patient to look away from the injection site. Position the eye adequately. At an area of 3.5 to 4.0 mm posterior to the limbus, mark an injection site.



6. Insert the injection needle into the vitreous cavity, avoiding the horizontal meridian and aiming towards the centre of the globe. Inject the recommended dose, with careful and constant pressure on the plunger. Do not apply additional pressure once the plunger has reached the bottom of the syringe. Do not inject any residual volume remaining in the syringe after the injection. Use a different scleral site for subsequent injections.

OTHER SOURCES OF INFORMATION

- The Royal College of Ophthalmologists guidance on topics such as Intravitreal Injection Therapy and Age-Related Macular Degeneration can be found at www.rcophth.ac.uk.
- Jaissle GB et al. Recommendation for the implementation of intravitreal injections- statement of the German Retina Society, the German Society of Ophthalmology (DOG) and the German Professional Association of Ophthalmologists (BVA). Klin Monbl Augenheilkd. 2005 May; 222(5):390-5. Article in German.

LOCAL SAFETY INFORMATION

Reporting 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 via HPRA Pharmacovigilance: Website: www.hpra.ie.

Adverse reactions should also be reported to bioepis.mi@medinformation.co.uk.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspect adverse reactions

Contact details for further information

If you have any further questions, or wish to receive more information or materials; please contact the medical information department of Samsung Bioepis at sb.armm@samsung.com.

