PRESCRIBER GUIDE TO INTRAVITREAL INJECTIONS WITH MYNZEPLI®▼ (AFLIBERCEPT)

2 mg dose (vial and prefilled syringe)

For further information and additional details , please refer to the relevant Summary of Product Characteristics (SmPC).

MYNZEPLI® is promoted in the Ireland by ADVANZ PHARMA Limited. ADVANZ PHARMA Limited is the Marketing Authorisation Holder.

This document is intended for healthcare professionals (HCPs) in Ireland only.

Job code: IE/AFL/NP/0004 | Date of preparation: February 2026

▼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 reactions via HPRA Pharmacovigilance. Website: **www.hpra.ie**.

Please call +353-1800-851-119 to report adverse events or product complaints or to speak to a Medical Information Specialist. Otherwise please email **medicalinformation@advanzpharma.com**

CONTENTS

MYNZEPLI®: PRESCRIBER GUIDE FOR INTRAVITREAL INJECTION

This guide provides important information on MYNZEPLI® 40 mg/ml solution for injection (2 mg aflibercept dose) in a vial and pre-filled syringe.

It includes information on the medication itself and how to correctly administer it to your patients.

For further information, please consult the summary of product characteristics (SmPC):

MYNZEPLI®
40 mg/ml solution for injection (2 mg dose)

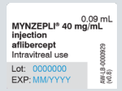
Scan or click here

MYNZEPLI®
40 mg/ml solution for injection in pre-filled syringe (2 mg dose)

Scan or click here

Please provide your patients with the relevant Patient Guide including its audio version (read out of the Patient Guide) and the product Patient Information Leaflet.

KEY SUMMARY INFORMATION

Aflibercept 40 mg/ml solution for injection (2 mg dose)			
Approved indications	Adults with: • Neovascular (wet) age-related macular degeneration (wAMD) • 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	2 mg		
Injection volume	0.05 ml		
Presentation	Pre-filled syringe and vial		
Vial packaging	Not currently available in Ireland	**Pre-filled syringe packaging**	
Vial	Not currently available in Ireland	**Pre-filled syringe**	
Label on vial	Not currently available in Ireland	**Label on pre-filled syringe**	

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

Contraindications

- Hypersensitivity to aflibercept or to any of the excipients
- Active or suspected ocular or periocular infection
- Active severe intraocular inflammation

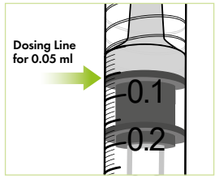
Key instructions for use

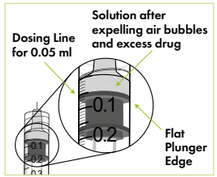
- The vial and pre-filled syringes come with excess volumes. Before injecting, the syringes with solution withdrawn from the vial and pre-filled syringes must be primed to the correct volume for injection according to the steps in the instructions for use
- Priming and setting the dose must be done using the steps below and in the instructions for use section
- Ensure proper aseptic technique including the use of broad-spectrum microbicide to minimise the risk of intraocular infection
- For intravitreal injection, a **30 G x ½ inch needle** should be used. Use of a smaller size injection needle (higher gauge) than the 30 G x ½ inch injection needle may result in increased injection forces, which may lead to more rapid and uncontrolled intravitreal drug delivery, potentially increasing the risk of ocular adverse events, such as those related to intraocular pressure

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

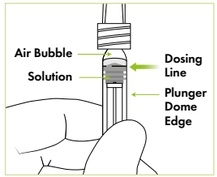
KEY INSTRUCTIONS FOR USE

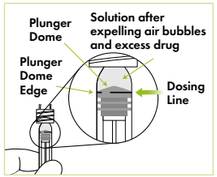
Correct plunger position: vial





Correct plunger position: pre-filled syringe





For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

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

- Eliminate all bubbles and expel excess medicinal product by slowly depressing the plunger so that the flat plunger edge aligns with the line that marks 0.05 ml on the syringe for the vial

Pre-filled syringe – aflibercept 40 mg/ml solution for injection (2 mg dose):

- Expel excess volume and air bubbles from the pre-filled syringe and adjust the base of the plunger dome (NOT the tip) to the dosing line before injection
- Push the plunger slowly and with constant pressure, and do not administer any residual volume remaining in the syringe after injection

Selected instructions for storage and handling

- Store in the refrigerator (2°C to 8°C)
- Prior to use, the unopened 40 mg/ml vial and pre-filled syringe may be kept in their cartons at room temperature (below 25°C) for up to 24 hours
- This medicine is **not** licensed for multi-dose, further compounding or vial splitting. Extraction of multiple doses from a pre-filled syringe/single vial can lead to contamination and subsequent infection

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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

Adverse event / risk	Measures to minimise 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 patients' vision and IOP after the injection
Medication error	Check the carton and the label on the medication to ensure the correct dose for your needs
Retinal pigment epithelial (RPE) tear	Review pigment epithelial detachment (PED) features for the 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 the 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
Embryo-foetotoxicity	Instruct patient to use effective contraception during treatment for at least 3 months after last intravitreal injection This medicine should not be used during pregnancy unless the potential benefit outweighs the potential risk to the foetus.
Exposure during breastfeeding	This medicine is not recommended in patients who are breastfeeding

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

After the injection

- **Evaluate vision immediately after injection** (hand movement or finger counting)
- **Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure**. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. Sterile equipment for paracentesis should be available in the case that paracentesis is required
- Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis (e.g. eye pain, redness of the eye, photophobia, blurring of vision) without delay

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

GENERAL INFORMATION

Before the start of treatment, a patient information guide, including an audio guide, and the Patient Information Leaflet, must be provided to each patient who is prescribed this medicine. The physician is responsible for providing the patient with these materials. This guide is available upon request to ADVANZ PHARMA: **medicalinformation@advanzpharma.com**.

In addition, the implications of anti-VEGF treatment should be explained with respect to the patient's individual condition.

Specifically, any signs and symptoms of serious adverse events and when to seek medical attention should be discussed with the patient.

The Summary of Product Characteristics, or SmPC, describes the properties of this medicine and the approved indications for use. It is an important source of information for healthcare professionals on how to use this medicine safely and effectively. You can access the SmPC via the link or by scanning the QR code on page 3.

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

ABOUT THIS MEDICINE

Presentations	Aflibercept 40 mg/ml pre-filled syringe and vial
Approved indications in adult (18 years and older) patients	• Neovascular (wet) AMD • Visual impairment due to diabetic macular oedema (DME) • Visual impairment due to macular oedema secondary to retinal vein occlusion (RVO), branch (BRVO) or central (CRVO) • Visual impairment due to myopic choroidal neovascularisation (mCNV)
Recommended dose	2 mg
Volume to inject	50 microliters or 0.05 ml
Posology for approved indications	Refer to the SmPC for complete information on posology and dosing for approved indications

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

PRODUCT INFORMATION

- This medicine is available in either a pre-filled syringe or a vial
- **It is for intravitreal injection only**. It must only be administered by a qualified physician who is experienced in administering intravitreal injections
- The solution is clear, colourless to pale yellow, and iso-osmotic
- The solution should be inspected visually for any foreign particulate matter and/or discolouration or any variation in physical appearance prior to administration. In the event of either being observed, discard the medicinal product
- The pre-filled syringe and the vials are for single use in one eye only
- This medicine is not licensed for multi-dose, further compounding or for vial splitting. Extraction of multiple doses from a pre-filled syringe /single vial can lead to contamination and subsequent infection
- The pre-filled syringes and each individual vial contain more than the recommended dose of 2 mg aflibercept (equivalent to 0.05 ml). The excess volume and any air bubbles in the syringes must be discarded before injecting

Special precautions for storage

- Store in a refrigerator (2°C to 8°C)
- Do not freeze
- Keep the pre-filled syringe in its blister and in the outer carton in order to protect from light
- Keep the vial in the outer carton in order to protect from light
- Prior to usage, the unopened vial or pre-filled syringe may be kept in its carton at room temperature (below 25°C) for up to 24 hours
- Do not open the sterile, pre-filled blister outside the clean administration room. After opening the blister or vial, proceed under aseptic conditions

Dosing recommendations

- For full details of the dosing schedule for each indication, please refer to section 4.2 of the relevant SmPC.

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

IMPORTANT SAFETY INFORMATION ABOUT THIS MEDICINE

Contraindications

This medicine is contraindicated in the following:

- Hypersensitivity to 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

Special warnings and precautions for use

Key signs and symptoms of intravitreal injection and related adverse events include:

- Endophthalmitis and intraocular inflammation (eye pain or increased discomfort, worsening eye redness, sensitivity to light, swelling of the eyelid, vision changes such as sudden decrease in vision or blurring of vision)
- Increased intraocular pressure (seeing halos around lights, eye pain, experiencing a red eye, nausea or vomiting, vision changes)
- Retinal pigment epithelial tear (sudden flashes of light, sudden appearance or an increase of floaters, curtain-like effect over a portion of the visual area, vision changes)
- Cataract (blurry vision, seeing shadows, less vivid lines and shapes, colour vision changes [e.g. colours looked 'washed out'])
- Immunogenicity
- Systemic effects
- Other:
  - **Women of childbearing potential**
    Women of childbearing potential have to use effective contraception during treatment and for at least 3 months after the last intravitreal injection of this medicine.
  - **Pregnancy**
    There are limited data on the use of aflibercept in pregnant women. This medicine 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 this medicine.

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

INSTRUCTIONS FOR USE/HANDLING

Injection preparation

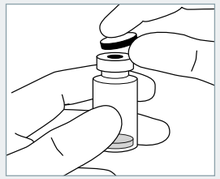
- When selecting the product to be administered, check the carton, the pre-filled syringe or vial and label to ensure it is the correct dose for your needs
- Intravitreal injections must be carried out according to current medical standards and applicable guidelines by a qualified physician, who is experienced in administering intravitreal injections
- Surgical hand disinfection, sterile gloves, a sterile drape, and a sterile 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 30 G x ½ inch needle may result in increased injection forces.

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

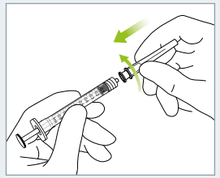
Instructions for use of vial

1. Check the carton, the vial, and label to ensure it is the correct dose for your needs
2. Remove the carton containing the vial from the refrigerator. Let the carton and its contents reach room temperature. Open the carton, remove the vial and place it upright on a flat surface to allow the solution to accumulate at the bottom of the vial. The solution should be inspected visually for any foreign particulate matter and/or discolouration or any variation in physical appearance prior to administration. In the event of either being observed, discard the medicinal product.

   An assistant should remove the plastic cap and disinfect the outer part of the rubber stopper of the vial



3. Attach the 18 G, 5 micron filter needle supplied in the carton to a 1 ml sterile Luer-lock syringe
4. While an assistant holds the vial, push the filter needle into the centre 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

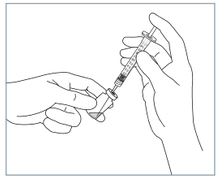


For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

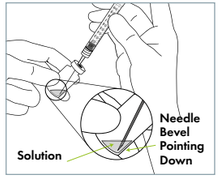
INSTRUCTIONS FOR USE OF VIAL CONT.

5 Using aseptic technique slowly withdraw all of the vial contents into the syringe, while an assistant keeps the vial in an upright position, slightly inclined to ease complete withdrawal. This helps to prevent air bubbles. To deter the introduction of air, ensure the bevel of the filter needle is submerged in the liquid.

The assistant should 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



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

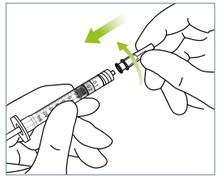


7 Remove the filter needle and properly dispose of it.

Note: Filter needle is **not** to be used for intravitreal injection

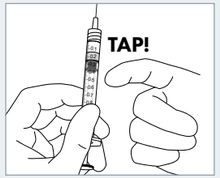
8 Using aseptic technique, firmly twist a 30 G x ½ inch injection needle onto the Luer-lock syringe tip.

Use of a smaller size injection needle (higher gauge) than the 30 G x ½ inch needle may result in increased injection forces



For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

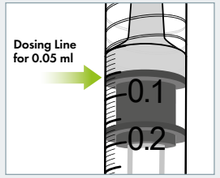
9 Holding the syringe with the needle pointing up, visually inspect the contents of the syringe. Check the syringe for air bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top



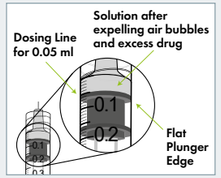
10 Correct handling of the filled syringe is important in order to avoid the risk of medication errors. This includes removal of the excess volume and air bubbles, in order to avoid overdosing.

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.

Accurate positioning of the plunger as shown in the diagrams is critical. Incorrect plunger positioning can lead to delivering more or less than the recommended dose.



11 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

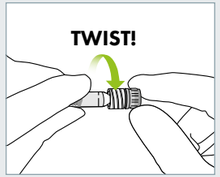


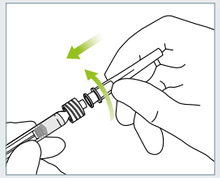
For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

Instructions for use of pre-filled syringe

The pre-filled syringe and contents must be inspected before use. Do not use the pre-filled syringe if any part is damaged or loose. Do not use it if the syringe cap is detached from the Luer-lock. Look for any particulate matter and/or unusual colour or any variation in physical appearance. If any of these are observed, do not use the product.

1. When ready to administer this medicine, an assistant should carefully open the carton and remove the sterilised blister. The assistant should carefully peel open the blister, ensuring the sterility of its contents. Keep the syringe in the sterile tray until you are ready for assembly.
2. Using aseptic technique, the injector should remove the syringe from the sterilised blister.
3. 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 forefinger. Please note: You should twist off (do not snap off) the syringe cap.
4. To avoid compromising the sterility of the product, do not pull back on the plunger.
5. Using aseptic technique, firmly twist the injection needle onto the Luer-lock syringe tip.



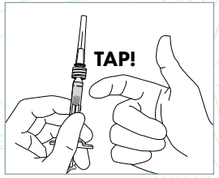


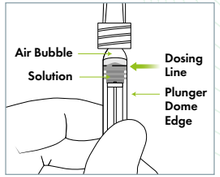
For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

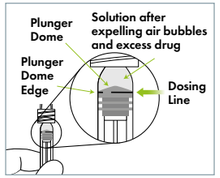
6. Holding the syringe with the needle pointing up, check the syringe for bubbles. If there are bubbles, gently tap the syringe with your finger until the bubbles rise to the top.
7. The excess volume must be discarded prior to administration. Eliminate all bubbles and **expel excess medicinal product by slowly depressing the plunger to align the base of the plunger dome (not the tip of the dome) with the dosing line on the syringe** (equivalent to 0.05 mL, i.e. 2 mg aflibercept).

   Note: This accurate positioning of the plunger is very important, because incorrect plunger positioning can lead to delivering more or less than the labelled dose.
8. Inject while pressing the plunger carefully and with constant pressure. Do not apply additional pressure once the plunger has reached the bottom of the syringe. **Do not administer any residual solution observed in the syringe**.
9. 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 should be disposed of in accordance with local requirements.







For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

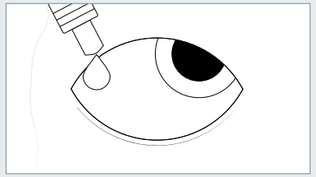
INJECTION PROCEDURE

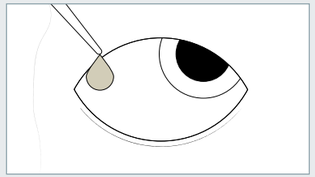
1. Administer topical anaesthesia

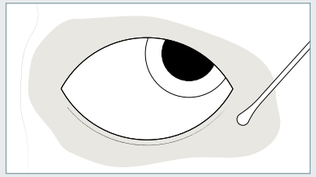
   Eye dilation prior to the injection procedure is **not** necessary

2. Instill disinfectant (e.g. 5% povidone iodine solution or equivalent) according to manufacturer's guidance. The disinfectant should be on the surface for the period of time specified in local clinical guidelines.

3. Apply disinfectant (e.g. 10% povidone iodine solution or equivalent) to periocular skin, eyelids, eyelid margins and eyelashes, avoiding excessive pressure on eyelids. The disinfectant should be on the surface for the period of time specified in local clinical guidelines







For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

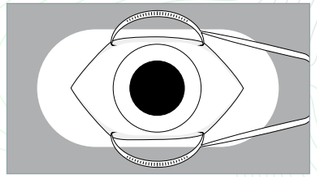
4. Cover with sterile drape and insert sterile lid speculum.

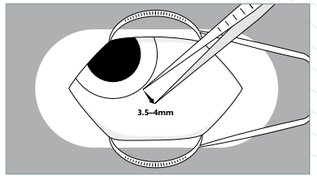
   A second application of disinfectant, e.g., 5% povidone iodine solution, may be made to the conjunctival sac. Disinfectant should be on the surface for the period of time specified in local clinical guidelines

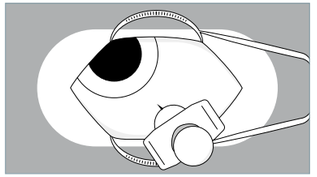
5. Tell your patient to look away from the injection site. Position the eye adequately. At an area 3.5 to 4.0 mm posterior to the limbus, mark an injection site

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

   The injection volume of 0.05 ml is then delivered, 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.







For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

AFTER THE INJECTION

- Evaluate vision immediately after injection (hand movement or finger counting)
- Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure. Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, sterile equipment for paracentesis should be available
- Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis (e.g. eye pain, redness of the eye, photophobia, blurring of vision) without delay
- Application of antibiotic eye drops after intravitreal injections should be according to local or national clinical guidelines and at the discretion of the treating clinician
- Please inform your patients that they could experience:
  - Bloodshot eye caused by bleeding from small blood vessels in the outer layers of the eye (conjunctival haemorrhage)
  - Moving spots in their vision (vitreous floaters)
  - Eye pain

These conditions normally go away a few days after the injection. Please advise your patients to seek medical attention if these conditions do not go away in a few days, or get worse.

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

ADVERSE REACTIONS

For comprehensive information about adverse reactions, please see section 4.8 of the SmPC.

Please inform your patients that they could experience the following adverse reactions:

- Endophthalmitis
- Cataract (traumatic, nuclear, subcapsular, cortical) or lenticular opacities
- Transient increase in intraocular pressure
- Tear of the retinal pigment epithelium
- Tear or detachment of the retina

To allow for early treatment, please also instruct your patients to report without delay any of the following symptoms, suggestive of serious adverse events:

- Increased eye pain
- Worsening redness of the eye
- Vision gets more blurred than usual or inability to see as well as usual
- Increased sensitivity to light
- Sudden appearance of floaters, flashes of light and/or obscured vision

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

MANAGEMENT OF INJECTION-RELATED ADVERSE REACTIONS

Make sure that, in case of any adverse reaction that concerns your patient, they have immediate access to an ophthalmologist.

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

For this reason, it is important to advise your patients to inform their doctor, pharmacist or nurse if they experience any side effects. This includes any possible side effects not listed in the Package Leaflet.

▼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 reactions via HPRA Pharmacovigilance. Website: **www.hpra.ie**.

Please call +353-1800-851-119 to report adverse events or product complaints to ADVANZ PHARMA or to speak to a Medical Information Specialist. Otherwise please email **medicalinformation@advanzpharma.com**.

By reporting side effects, patients can help provide more information on the safety of this medicine.

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

Notes

For further information and additional details, please refer to the relevant Summary of Product Characteristics (SmPC).

This Risk Management material fulfils the conditions of the marketing authorisation and has been approved by the HPRA. Version 1.0, February 2026.

For any medical information requests, please contact:

Telephone: +353-1800-851-119

Email: medicalinformation@advanzpharma.com

Job code: IE/AFL/NP/0004 | Date of preparation: February 2026