SANDOZ

Sandoz Patient Safety

Aflibercept

40 mg/mL

Solution for injection

Patient 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
Document status:	Final
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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 how to prepare for treatment, recognise serious side effects and know when to seek urgent attention from your doctor.
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Patient Guide

Please also observe the package leaflet for aflibercept included with your medicine.

This Guide is also available as a digital version and an audio version. The digital and audio versions of the Guide, and the package leaflet, are available online at:

https://www.afliberceptrowex.eu
www.hpra.ie (digital version of the Patient Guide only)

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What is aflibercept?

Aflibercept belongs to a drug group known as anti-VEGFs. Anti-VEGF is the abbreviation for anti-vascular endothelial growth factor, which describes how aflibercept works to protect your vision. Aflibercept blocks VEGF, and this effect helps to reduce fluids in the retina, which can lead to improvements and maintenance of vision.

Aflibercept is a solution that is injected into the eye. It is available as a 2 mg dosage. Your doctor will determine which dosage is most appropriate for your individual situation.

The frequency of injections will be based on the condition of your eye. Depending on your eye disease and the dosage specified by the doctor, the length of the intervals between injections may vary.

Your doctor will recommend a treatment schedule for you. It is very important that you follow it.

For whom is aflibercept suitable?

Aflibercept 2 mg is suitable for treating the following eye disorders in adults:

- neovascular (wet) age-related macular degeneration (AMD),
- impaired vision due to macular edema from retinal vein occlusion (RVO) (branch retinal vein occlusion [BRVO] or central retinal vein occlusion [CRVO]),
- impaired vision due to diabetic macular edema (DME),
- impaired vision due to myopic choroidal neovascularization (mCNV).

What should your doctor know before you are treated with aflibercept?

Before starting treatment with aflibercept, it is important to tell your doctor if:

- You have inflammation or infection in or around the eye.
- You currently have redness in your eye or your eye is painful.
- You think you could be allergic (hypersensitive) to iodine, pain medication, or any of the other ingredients of aflibercept.
- You have experienced any discomfort or complications from previous eye injections.
- You have glaucoma or you have had increased intraocular pressure before (pressure inside the eye).
- You see or have seen flashes of light or floaters (dark floating spots).
- You are currently taking other medications, prescription and non-prescription drugs.
- You have had or are scheduled to have eye surgery within 4 weeks before or after aflibercept treatment.
- You are pregnant, or are planning to become pregnant, or are breastfeeding. There is only very little information available about the safety of using aflibercept in pregnant women. Aflibercept 2 mg should not be used during pregnancy unless the expected benefit outweighs the potential risk to the fetus. Discuss this with your doctor before taking aflibercept.
- Women of childbearing potential should use reliable contraceptive methods during treatment with aflibercept. If you are being treated with the **aflibercept 2 mg dosage**, you should use **reliable contraception for at least 3 months after the last injection**.

- Low quantities of aflibercept can be transferred to breast milk. The effects of aflibercept on nursing infants/children are not known. Use of aflibercept is not recommended during breastfeeding.

How do I prepare for my aflibercept treatment visit?

Your doctor may ask you to use eye drops a few days before your visit. Blurring of vision may occur after treatment, so you should not drive. Have an acquaintance or family member take you to your appointment or organize another way to get there and back home. You should not wear any makeup on the day of your appointment.

What should I expect after treatment with aflibercept?

- Your doctor will do some eye tests after the aflibercept injection, which may include a measurement of your intraocular pressure (pressure inside the eye).
- Blurring of vision may occur after the injection. Therefore you should not drive until your vision returns to normal.
- Over the next few days, you may have bloodshot eyes or see floaters in your visual field. Please contact your doctor if these do not go away within a few days or if they get worse.
- Some people may experience mild pain or discomfort in the eye after the injection. Please contact your doctor if the pain does not go away within a few days or gets worse.

What are signs and symptoms of serious side effects?

If you notice any of the signs or symptoms listed in the table below, please contact your doctor immediately, as these may be signs of a serious complication of the treatment:

Disease	Some possible signs or symptoms
Infection or inflammation in the eye	• Eye pain or increased discomfort • Worsening redness of the eye • Sensitivity to light • Swelling of the eyelid • Changes in vision, such as a sudden worsening of vision or blurred vision
Clouded lens (cataract)	• Blurred vision • Seeing shadows • Less clearly recognizable lines and forms • Change in color vision (e.g., colors seem “washed out”)
Increase in intraocular pressure	• Halos around lights • Eye pain

	• Eye redness • Nausea or vomiting • Vision changes
Detachment or tearing of a retinal layer	• Sudden flashes of light • Sudden occurrence or an increase in floaters (dark, floating spots) • Curtain-like effect over a part of the visual field • Vision changes

You will find a complete list of side effects in the information for the user (package leaflet) that is attached to the patient guide. You can also access the package leaflet via the link to the website listed in this guide or also ask your doctor.

▼ This medicine is subject to additional monitoring. If you get any side effects, talk to your doctor. This will allow for quick identification of new safety information. You can help by reporting any side effects directly via HPRA Pharmacovigilance. Website: www.hpra.ie.

You can also report side effects directly to:
Rowex Ltd., Tel: 1800 83 20 83; e-mail: adverse.event.ireland@sandoz.net

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

If you have any questions, your doctor or healthcare professional is the best person to contact. They have considerable experience and are aware of your individual situation, so they can give you the answers you need.

Other information

Your eye center is: _____

_____

Contact: _____

Phone: _____

Address: _____

E-mail: _____

Stamp: