

Package leaflet: Information for the adult patient

Opuviz™ 40 mg/mL

solution for injection in a vial afilbercept



▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Opuviz is and what it is used for
2. What you need to know before you are given Opuviz
3. How you will be given Opuviz
4. Possible side effects
5. How to store Opuviz
6. Contents of the pack and other information

1. What Opuviz is and what it is used for

Opuviz is a solution which is injected into the eye to treat eye conditions in adults called

- neovascular (wet) age-related macular degeneration (wet AMD),
- impaired vision due to macular oedema secondary to retinal vein occlusion (branch RVO (BRVO) or central RVO (CRVO)),
- impaired vision due to diabetic macular oedema (DME),
- impaired vision due to myopic choroidal neovascularisation (myopic CNV).

Afilbercept, the active substance in Opuviz, blocks the activity of a group of factors, known as Vascular Endothelial Growth Factor A (VEGF-A) and Placental Growth Factor (PlGF).

In patients with wet AMD and myopic CNV, these factors, in excess are involved in the abnormal formation of new blood vessels in the eye. These new blood vessels can cause the leak of blood components into the eye and eventual damage to tissues in the eye responsible for vision.

In patients with CRVO, a blockage occurs in the main blood vessel that transports blood away from the retina. VEGF levels are elevated in response causing the leakage of fluid into the retina and thereby causing a swelling of the macula, (the portion of the retina responsible for fine vision), which is called macular oedema. When the macula swells with fluid, central vision becomes blurry.

In patients with BRVO, one or more branches of the main blood vessel that transports blood away from the retina is blocked. VEGF levels are elevated in response causing the leakage of fluid into the retina and thereby causing macular oedema.

Diabetic macular oedema is a swelling of the retina occurring in patients with diabetes due to leaking of fluid from blood vessels within the macula. The macula is the portion of retina responsible for fine vision. When the macula swells with fluid, central vision becomes blurry.

Opuviz has been shown to stop the growth of new abnormal blood vessels in the eye which often leak fluid or bleed. Opuviz can help to stabilise, and in many cases, improve the vision loss related to wet AMD, CRVO, BRVO, DME and myopic CNV.

2. What you need to know before you are given Opuviz

You will not be given Opuviz

- if you are allergic to aflibercept or any of the other ingredients of this medicine (listed in section 6).
- if you have an active or suspected infection in or around the eye (ocular or periocular infection).
- if you have severe inflammation of the eye (indicated by pain or redness)

Warnings and precautions

Talk to your doctor before you are given Opuviz:

- if you have glaucoma.
- if you have a history of seeing flashes of light or floaters and if you have a sudden increase of size and number of floaters.
- if surgery was performed or is planned on your eye within the previous or next four weeks.
- if you have a severe form of CRVO or BRVO (ischaemic CRVO or BRVO), treatment with Opuviz is not recommended.

Furthermore, it is important for you to know that:

- the safety and efficacy of Opuviz when administered to both eyes at the same time has not been studied and if used in this way may lead to an increased risk of experiencing side effects.
- injections with Opuviz may cause an increase in eye pressure (intraocular pressure) in some patients within 60 minutes of the injection. Your doctor will monitor this after each injection.
- if you develop an infection or inflammation inside the eye (endophthalmitis) or other complications, you may have eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, and increased sensitivity to light. It is important to have any symptoms diagnosed and treated as soon as possible.
- your doctor will check whether you have other risk factors that may increase the chance of a tear or detachment of one of the layers at the back of the eye (retinal detachment or tear, and retinal pigment epithelial detachment or tear), in which case Opuviz must be given with caution.
- Opuviz should not be used in pregnancy unless the potential benefit outweighs the potential risk to the unborn child.
- women of childbearing potential have to use effective contraception during treatment and for at least three further months after the last injection of Opuviz.

The systemic use of VEGF inhibitors, substances similar to those contained in Opuviz, is potentially related to the risk of blood clots blocking blood vessels (arterial thromboembolic events) which may lead to heart attack or stroke. There is a theoretical risk of such events following injection of Opuviz into the eye. There are limited data on safety in treating patients with CRVO, BRVO, DME and myopic CNV who have had a stroke or a

mini-stroke (transient ischaemic attack) or a heart attack within the last 6 months. If any of these apply to you, Opuviz will be given with caution.

There is only limited experience in the treatment of

- patients with DME due to type I diabetes.
- diabetics with very high average blood sugar values (HbA1c over 12%).
- diabetics with an eye disease caused by diabetes called proliferative diabetic retinopathy.

There is no experience in the treatment of

- patients with acute infections.
- patients with other eye conditions such as a detachment of the retina or a hole in the macula.
- diabetics with uncontrolled high blood pressure.
- non-Asian patients with myopic CNV
- patients previously treated for myopic CNV.
- patients with damage outside the central part of the macula (extrafoveal lesions) for myopic CNV.

If any of the above applies to you, your doctor will consider this lack of information when treating you with Opuviz.

Children and adolescents

The use of Opuviz in children or adolescents under 18 has not been studied because wet AMD, CRVO, BRVO, DME and myopic CNV occur mainly in adults. Therefore, its use in this age group is not relevant.

Other medicines and Opuviz

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

- Women of childbearing potential have to use effective contraception during treatment and for at least three further months after the last injection of Opuviz.

- There is no experience of using Opuviz in pregnant women. Opuviz should not be used during pregnancy unless the potential benefit outweighs the potential risk to the unborn child. If you are pregnant or planning to become pregnant, discuss this with your doctor before treatment with Opuviz.

- Small amounts of aflibercept may pass into human milk. The effects on breast-fed newborns/infants are unknown. Opuviz is not recommended during breast-feeding. If you are a breast-feeding woman, discuss this with your doctor before treatment with Opuviz.

Driving and using machines

After your injection with Opuviz, you may experience some temporary visual disturbances. Do not drive or use machines as long as these last.

Opuviz contains

- This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.
- 0.015 mg of polysorbate 20 in each 0.05 ml dose which is equivalent to 0.3 mg/ml. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How you will be given Opuviz

A healthcare professional experienced in giving eye injections will inject Opuviz into your eye under aseptic (clean and sterile) conditions.

The recommended dose is 2 mg aflibercept (0.05 mL).

Opuviz is given as an injection into your eye (intravitreal injection).

Before the injection your healthcare professional will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your healthcare professional will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.

wet AMD

Patients with wet AMD will be treated with one injection per month for three consecutive doses, followed by another injection after a further two months.

Your doctor will then decide whether the treatment interval between injections may be kept at every two months or be gradually extended in 2- or 4-weekly intervals if your condition has been stable.

If your condition worsens, the interval between injections can be shortened.

Unless you experience any problems or are advised differently by your doctor, there is no need for you to see your doctor between the injections.

Macular oedema secondary to RVO (branch RVO or central RVO)

Your doctor will determine the most appropriate treatment schedule for you. You will start your treatment with a series of monthly Opuviz injections.

The interval between two injections should not be shorter than one month.

Your doctor may decide to stop treatment with Opuviz, if you are not benefiting from continued treatment.

Your treatment will continue with monthly injections until your condition is stable. Three or more monthly injections may be needed.

Your doctor will monitor your response to treatment and may continue your treatment by gradually increasing the interval between your injections to maintain a stable condition. If your condition starts to worsen with a longer treatment interval, your doctor will shorten the interval accordingly.

Based on your response to treatment your doctor will decide on the schedule for follow up examinations and treatments.

Diabetic macular oedema (DME)

Patients with DME will be treated with one injection per month for the first five consecutive doses followed by one injection every two months thereafter.

Treatment interval may be kept at every two months or adjusted to your condition, based on your doctor's examination. Your doctor will decide on the schedule for follow up examinations.

Your doctor may decide to stop treatment with Opuviz if it is determined that you are not benefiting from continued treatment.

Myopic CNV

Patients with myopic CNV will be treated with one single injection. You will receive further injections only if your doctor's examinations reveal that your condition has not improved.

The interval between two injections should not be shorter than one month. If your condition goes away and then comes back, your doctor may re-start the treatment.

Your doctor will decide on the schedule for follow up examinations.

Detailed instructions for use are given at the end of the leaflet under "How to prepare and administer Opuviz to adults".

If a dose of Opuviz is missed

Make a new appointment for an examination and injection.

Stopping treatment with Opuviz

Consult your doctor before stopping the treatment.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Allergic reactions (hypersensitivity) could potentially occur. **These may be serious and require that you contact your doctor immediately.**

With administration of Opuviz, there may be some side effects affecting the eyes which are due to the injection procedure. Some of these may be **serious and include blindness, a serious infection or inflammation inside the eye** (endophthalmitis), **detachment, tear or bleeding of the light-sensitive layer at the back of the eye** (retinal detachment or tear), **clouding of the lens** (cataract), **bleeding in the eye** (vitreous haemorrhage), **detachment of the gel-like substance inside the eye from the retina** (vitreous detachment) and **increase of pressure inside the eye**, see section 2. These serious side effects affecting the eyes occurred in less than 1 in 1,900 injections in clinical studies.

If you experience a sudden decrease in vision, or an increase in pain and redness in your eye after your injection, **contact your doctor immediately.**

List of side effects reported

The following is a list of the side effects reported to be possibly related to the injection procedure or to the medicine. Please do not get alarmed, you might not experience any of these. Always discuss any suspected side effects with your doctor.

Very common side effects (*may affect more than 1 in 10 people*):

- deterioration of eyesight
- bleeding in the back of the eye (retinal haemorrhage)
- bloodshot eye caused by bleeding from small blood vessels in the outer layers of the eye
- eye pain

Common side effects (*may affect up to 1 in 10 people*):

- detachment or tear of one of the layers in the back of the eye, resulting in flashes of light with floaters sometimes progressing to a loss of vision (retinal pigment epithelial tear*/detachment, retinal detachment/tear)
- *Conditions known to be associated with wet AMD; observed in wet AMD patients only.
- degeneration of the retina causing disturbed vision
- bleeding in the eye (vitreous haemorrhage)
- certain forms of clouding of the lens (cataract)
- damage to the front layer of the eyeball (the cornea)
- increase in eye pressure
- moving spots in vision (floaters)
- detachment of the gel-like substance inside the eye from the retina (vitreous detachment, resulting in flashes of light with floaters)
- a feeling of having something in the eye
- increased tear production
- swelling of the eyelid
- bleeding at the injection site
- redness of the eye

Uncommon side effects (*may affect up to 1 in 100 people*):

- allergic reactions (hypersensitivity)**
- ** Allergic reactions like rash, itching (pruritus), hives (urticaria), and a few cases of severe allergy (anaphylactic/anaphylactoid) reactions were reported.
- serious inflammation or infection inside the eye (endophthalmitis)
- inflammation in the iris or other parts of the eye (iritis, uveitis, iridocyclitis, anterior chamber flare)
- abnormal sensation in the eye
- eyelid irritation
- swelling of the front layer of the eyeball (cornea)

Rare side effects (*may affect up to 1 in 1,000 people*):

- blindness
- clouding of the lens due to injury (traumatic cataract)
- inflammation of the gel-like substance inside the eye
- pus in the eye

Not known (*frequency cannot be estimated from the available data*):

- inflammation of the white part of the eye associated with redness and pain (scleritis)

In the clinical trials, there was an increased incidence of bleeding from small blood vessels in the outer layers of the eye (conjunctival haemorrhage) in patients with wet AMD receiving blood thinners. This increased incidence was comparable between patients treated with ranibizumab and aflibercept.

The systemic use of VEGF inhibitors, substances similar to those contained in Opuviz, is potentially related to the risk of blood clots blocking blood vessels (arterial thromboembolic events) which may lead to heart attack or stroke. There is a theoretical risk of such events following injection of Opuviz into the eye.

As with all therapeutic proteins, there is a possibility for an immune reaction (formation of antibodies) with Opuviz.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Opuviz

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C). Do not freeze.
- The unopened vial may be stored outside the refrigerator at room temperature up to 30°C for a period of up to 3 days.
- Store in the original package in order to protect from light.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Opuviz contains

- The active substance is: aflibercept. One vial contains an extractable volume of at least 0.1 mL, equivalent to at least 4 mg aflibercept. One vial delivers a dose of 2 mg aflibercept in 0.05 mL.
- The other ingredients are: Sodium dihydrogen phosphate dihydrate, di-sodium hydrogen phosphate dihydrate, sucrose, polysorbate 20 (E 432), water for injections.

See 'Opuviz contains' in section 2 for more information.

What Opuviz looks like and contents of the pack

Opuviz is a solution for injection (injection) in a vial. The solution is a clear, colourless to pale yellow.

Pack size of 1 vial + 1 filter needle.

Pack size of 1 vial.

Marketing Authorisation Holder and Manufacturer

Samsung Bioepis UK Limited
5th floor, Profile West, 950 Great West Road
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Tel: +44 20 8 232 8802

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

How to prepare and administer Opuviz to adults

The vial is for single use in one eye only.

The vial contains more than the recommended dose of 2 mg aflibercept (equivalent to 0.05 mL). The excess volume must be discarded prior to administration.

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.

Vial-only pack

For preparation and intravitreal injection, the following medical devices for single use are needed:

- a 5 µm filter needle (18-G x 1½")
- an injection needle (30-G x ½")

- a 1 mL sterile syringe (including a 0.05 mL mark)

These medical devices are not included within this pack.

Vial + filter needle pack

For preparation and intravitreal injection, the following medical devices for single use are needed:

- a 5 µm filter needle (18-G x 1½", 1.2 mm x 40 mm, provided)
- an injection needle (30-G x ½", not included within this pack)

- a 1 mL sterile syringe (including a 0.05 mL mark, not included within this pack)

Filter needle:

Filter needle, not for skin injection. Do not autoclave the filter needle.

Do not use it if individual packaging is damaged. Discard the used filter needle in approved sharps collector.

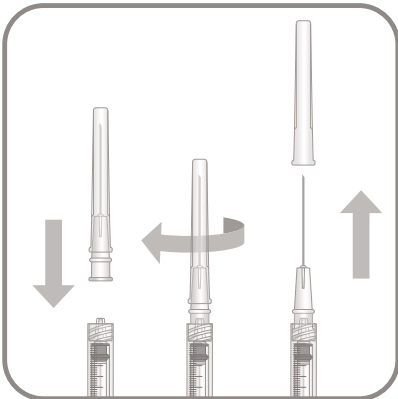
Caution: Re use of the filter needle may lead to infection or other illness/injury. For the intravitreal injection, a 30 G x ½ inch injection needle should be used.

Instructions for use of vial:

1. Remove the plastic cap and disinfect the outer part of the rubber stopper of the vial.

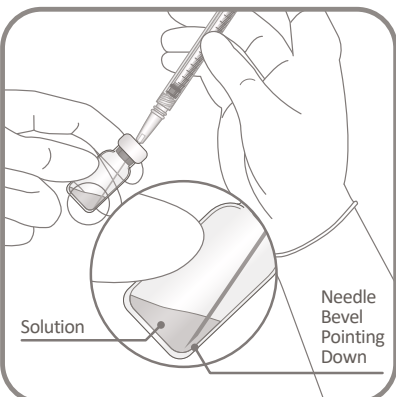
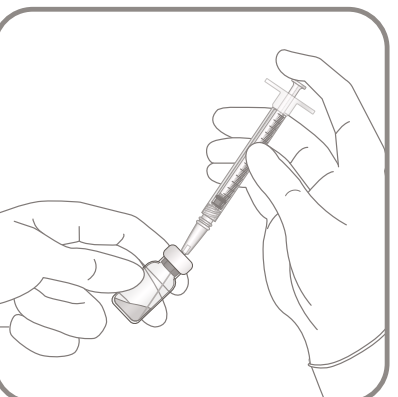


2. Attach the 18 G x 1 ½ inch, 5 micron filter needle to a 1 mL sterile syringe.

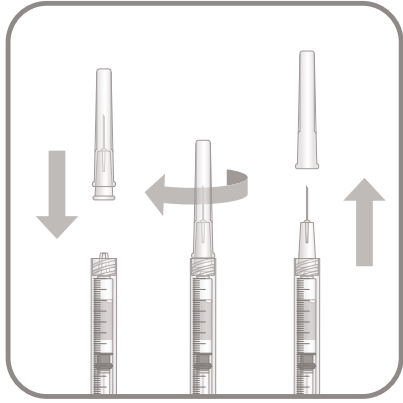


3. Push the filter needle into the centre of the vial stopper until the needle is completely inserted into the vial and the tip touches the bottom or bottom edge of the vial.

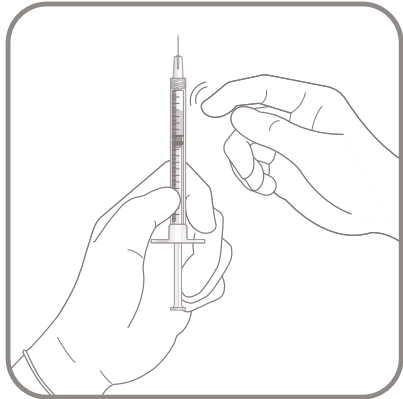
4. Using aseptic technique withdraw all of the Opuviz vial contents into the syringe, keeping the vial in an upright position, slightly inclined to ease complete withdrawal. To deter the introduction of air, ensure the bevel of the filter needle is submerged into the liquid. Continue to tilt the vial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



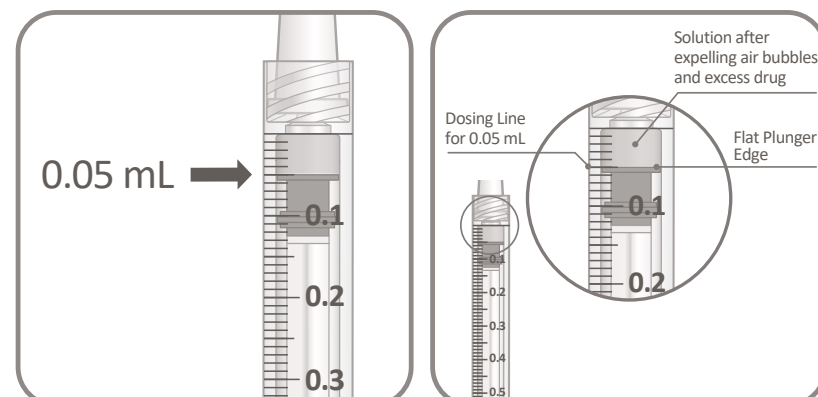
5. Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle.
6. Remove the filter needle and properly dispose of it.
Note: Filter needle is not to be used for intravitreal injection.
7. Using aseptic technique, firmly twist a 30 G x ½ inch injection needle onto the syringe tip.



8. 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.



9. 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.



10. 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.