100 mm

240 mm

Aflivis™

Aflibercept INN Sterile Solution for Intravitreal Injection

DESCRIPTION

Aflivis™ is a preparation of Aflibercept for intravitreal injection. **Aflivis™** is a recombinant fusion protein consisting of portions of human VEGF receptors 1 and 2 extracellular domains fused to the Fc portion of human IgG1 formulated as an iso-osmotic solution for intravitreal administration. Vascular endothelial growth factor-A (VEGF-A) and placental growth factor (PIGF) are members of the VEGF family of angiogenic factors that can act as mitogenic, chemotactic, and vascular permeability factors for endothelial cells. VEGF acts via two receptor tyrosine kinases, VEGFR-1 and VEGFR-2, present on the surface of endothelial cells. PIGF binds only to VEGFR-1, which is also present on the surface of leucocytes. Activation of these receptors by VEGF-A can result in neovascularization and vascular permeability. **Aflivis™** acts as a soluble decoy receptor that binds VEGF-A and PIGF, and thereby can inhibit the binding and activation of these cognate VEGF receptors.

INDICATIONS

Aflivis™ is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)
- Retinopathy of Prematurity (ROP)

DOSAGE AND ADMINISTRATION

- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- The recommended dose for **Aflivis™** is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months).
- Although **Aflivis™** may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when **Aflivis™** was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 12 weeks (3 months).
- Although not as effective as the recommended every 8 week dosing regimen, patients may also be treated with one dose every 12 weeks after one year of effective therapy. Patients should be assessed regularly.
- Macular Edema Following Retinal Vein Occlusion (RVO)
- The recommended dose for **Aflivis™** is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection once every 4 weeks (approximately every 25 days, monthly).
- Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)
- The recommended dose for **Aflivis™** is 2 mg (0.05 mL of 40 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL of 40 mg/mL solution) via intravitreal injection once every 8 weeks (2 months).
- Although **Aflivis™** may be dosed as frequently as 2 mg every 4 weeks (approximately every 25 days, monthly), additional efficacy was not demonstrated in most patients when **Aflivis™** was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 week (monthly) dosing after the first 20 weeks (5 months).
- Retinopathy of Prematurity (ROP)
- The recommended dose for **Aflivis™** is 0.4 mg (0.01 mL or 10 microliters of 40 mg/mL solution) administered by intravitreal injection. Treatment may be given bilaterally on the same day. Injections may be repeated in each eye. The treatment interval between doses injected into the same eye should be at least 10 days.

CONTRAINDICATIONS

- Ocular or periocular infection
- Active intraocular inflammation
- Hypersensitivity

SIDE EFFECTS

The most common adverse reactions (≥5%) reported in patients receiving Aflibercept were conjunctival hemorrhage, eye pain, cataract, vitreous detachment, vitreous floaters, and intraocular pressure increased.

PRECAUTION AND WARNING

- Endophthalmitis, retinal detachments, and retinal vasculitis with or withoutocclusion may occur following intravitreal injections. Patients and/orcaregivers should be instructed to report any signs and/or symptomssuggestive of endophthalmitis, retinal detachment, or retinal vasculitiswithout delay and should be managed appropriately.
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
- In infants with ROP, treatment with Aflibercept will necessitate extended periods of ROP monitoring
- There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors.

USE IN PREGNANCY AND LACTATION

Adequate and well-controlled studies with Aflibercept have not been conducted in pregnant women. Aflibercept should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. There is no information regarding the presence of Aflibercept in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production/excretion. Aflibercept is not recommended during breastfeeding.

PEDIATRIC USE

The safety and effectiveness of Aflibercept have been demonstrated in preterm infants with ROP.

DRUG INTERACTION

No specific drug-interaction information is provided in the supplied prescribing information.

OVERDOSE

Overdosing with increased injection volume may increase intraocular pressure. Therefore, in case of overdosage, intraocular pressure should be monitored and if deemed necessary by the treating physician, adequate treatment should be initiated.

PHARMACEUTICAL PRECAUTION

It should be stored at 2 °C–8 °C and should not be frozen.. Protect from light. Store in the original carton. Each P**FS** is for single-eye use only. Do not store in wet place. Keep away from light. Keep out of reach of children.

PACKAGING

Aflivis™ Solution for Injection:

Each box contains 1 pre-filled syringe. Each prefilled syringe contains Aflibercept INN 2 mg in 0.05 mL Solution

SK+F BIOLOGICS
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM3442 V01

PM SPECIFICATION

Creative ID: CSD_04

Job Name: Aflivis Leaflet		**Size:** L - 330 mm, W - 100 mm	**Paper:** 60 gsm offset paper
No. of Color: 2 (Extra)	**Lamination:** N/A	**Loading Process:** N/A	**Others:** N/A
Process Color Print: N/A	**Pantone Color Code**	Black C	2347 C

	Creative Service Department	Marketing Department	PD/QC/Contract Customer	Approved By
Comments				
Signature & Date				