Agafi™

Aflibercept Intravitreal Injection

2220

Presentation
Agafi™ Intravitreal Injection: Each vial contains Aflibercept INN 2 mg in 0.05 ml sterile solution for Intravitreal Injection.

Description
Aflibercept 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. Aflibercept is a dimeric glycoprotein with a protein molecular weight of 97 kilodaltons (kDa) and contains glycosylation, constituting an additional 15% of the total molecular mass, resulting in a total molecular weight of 115 kDa. Aflibercept is produced in recombinant Chinese hamster ovary (CHO) cells. Aflibercept acts as a soluble decoy receptor that binds VEGF-A and PlGF, and thereby can inhibit the binding and activation of these cognate VEGF receptors.

Indication and usage
Agafi is indicated for adults for the treatment of
- 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)

Dosage and administrations
Neovascular (Wet) Age-Related Macular Degeneration (AMD)
• The recommended dose for Aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 3 months, followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).
• Although Aflibercept 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 Aflibercept was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 weeks (monthly) dosing after the first 12 weeks (3 months).
• Although not as effective as the recommended every 8 weeks 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 Aflibercept is 2 mg (0.05 mL) 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 Aflibercept is 2 mg (0.05 mL) administered by intravitreal injection every 4 weeks (approximately every 28 days, monthly) for the first 5 injections followed by 2 mg (0.05 mL) via intravitreal injection once every 8 weeks (2 months).
• Although Aflibercept 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 Aflibercept was dosed every 4 weeks compared to every 8 weeks. Some patients may need every 4 weeks (monthly) dosing after the first 20 weeks (5 months).

Important Injection Instructions
For ophthalmic intravitreal injection Afflibercept must only be administered by a qualified physician. Vial: A 5-micron sterile filter needle (18-gauge × 1½-inch), a 1-mL Luer lock syringe and a 30-gauge × ½-inch sterile injection needle are needed which are provided with commercial pack.

Warnings and precautions
Endophthalmitis, retinal pigment epithelial tear and retinal detachments may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately.
• Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
• There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors

Contraindications
Hypersensitivity to the active substance aflibercept or to any of the excipients Active or suspected ocular or periocular infection. Active severe intraocular inflammation.

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

Use in specific populations
Pregnancy: Adequate and well-controlled studies with Aflibercept have not been conducted in pregnant women. Aflibercept produced adverse embryofetal effects in rabbits, including external, visceral, and skeletal malformations
Lactation: 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.
Pediatric Use: The safety and effectiveness of Aflibercept in pediatric patients have not been established.
Females and Males of Reproductive Potential: Females of reproductive potential are advised to use effective contraception prior to the initial dose, during treatment, and for at least 3 months after the last intravitreal injection of Aflibercept.
Infertility: There are no data regarding the effects of Aflibercept on human fertility

Drug Interaction
There are no data available regarding the drug interaction of Aflibercept.

Storage
Store at 2°C to 8°C in a refrigerator. Do not freeze. Keep away from light and out of the reach of children.

Commercial pack
Agafi™ Intravitreal Injection: Each box contains one vial of 0.05 mL intravitreal injection.

Manufactured by
Incepta Pharmaceuticals Ltd
Savar, Dhaka, Bangladesh
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