100 mm

330 mm

Farimab™

Faricimab Solution for Injection for Intravitreal Use

DESCRIPTION

Farimab™ is a sterile solution of faricimab for intravitreal injection. It is a humanised bispecific antibody that acts by simultaneously inhibiting two signalling pathways through binding to vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2). Inhibition of VEGF-A suppresses endothelial cell proliferation, pathological neovascularisation and increased vascular permeability. Inhibition of Ang-2 is thought to promote vascular stability and reduce the sensitivity of blood vessels to the effects of VEGF-A. Ang-2 levels are increased in some patients with neovascular age-related macular degeneration (nAMD), diabetic macular oedema (DME) and retinal vein occlusion (RVO).; however, the precise contribution of Ang-2 inhibition to the overall clinical response in these conditions has not yet been established.

INDICATIONS

Farimab™ is indicated for the treatment of patients with-

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- Diabetic Macular Edema (DME)
- Macular Edema Following Retinal Vein Occlusion (RVO)

DOSAGE AND ADMINISTRATION

Farimab™ is intended only for intravitreal injection and must be administered by a qualified physician.

- **Neovascular (Wet) Age-Related Macular Degeneration (nAMD):** The recommended dose is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly) for the first 4 doses, followed by optical coherence tomography and visual acuity evaluations 8 and 12 weeks later to inform whether to give a 6 mg dose via intravitreal injection on one of the following three regimens: 1) Weeks 28 and 44; 2) Weeks 24, 36 and 48; or 3) Weeks 20, 28, 36 and 44. Although additional efficacy was not demonstrated in most patients when VABYSMO was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.
- **Diabetic Macular Edema (DME):** Recommended to be dosed by following one of these two dose regimens: 1) 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection every 4 weeks (approximately every 28 days ± 7 days, monthly) for at least 4 doses. If after at least 4 doses, resolution of edema based on the central subfield thickness (CST) of the macula as measured by optical coherence tomography is achieved, then the interval of dosing may be modified by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on CST and visual acuity evaluations; or 2) 6 mg dose of **Farimab™** can be administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injection at intervals of every 8 weeks (2 months). Although additional efficacy was not demonstrated in most patients when **Farimab™** was dosed every 4 weeks compared to every 8 weeks, some patients may need every 4 week (monthly) dosing after the first 4 doses. Patients should be assessed regularly.
- **Macular Edema Following Retinal Vein Occlusion (RVO):** The recommended dose is 6 mg (0.05 mL of 120 mg/mL) administered by intravitreal injection every 4 weeks (approximately every 28 ± 7 days, monthly).

CONTRAINDICATIONS

Faricimab is contraindicated in patients with ocular or periocular infections, active intraocular inflammation, or known hypersensitivity to faricimab or any of the excipients. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation.

SIDE EFFECTS

The most common adverse reactions (≥ 5%) reported in patients receiving faricimab are cataract and conjunctival hemorrhage.

PRECAUTION AND WARNING

- Endophthalmitis and retinal detachments may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay, to permit prompt and appropriate management.
- Increases in intraocular pressure have been seen within 60 minutes of an intravitreal injection.
- There is a potential risk of arterial thromboembolic events (ATEs) associated with VEGF inhibition.

USE IN PREGNANCY AND LACTATION

No adequate studies of faricimab in pregnant women have been conducted. Based on its mechanism (VEGF/Ang-2 inhibition), potential risks to embryo-fetal development and female fertility cannot be excluded. Use during pregnancy should be reserved for situations in which the potential benefit is judged to outweigh the potential risk to the fetus. No data are available on the presence of faricimab in human milk, its effects on the breastfed infant, or milk production. The benefits of breastfeeding should be considered alongside the maternal clinical need for faricimab and any potential risks to the breastfed child.

PEDIATRIC USE

The safety and efficacy of faricimab in pediatric patients have not been established.

DRUG INTERACTION

No interaction studies have been performed. Based on the biotransformation and elimination of faricimab, no interactions are expected. However, faricimab should not be administered concurrently with other systemic or ocular anti-VEGF medicinal products.

OVERDOSE

Overdosing with greater than recommended injection volume may increase intraocular pressure. In the event of overdose, IOP should be monitored and, if deemed necessary by the treating physician, appropriate treatment should be initiated.

PHARMACEUTICAL PRECAUTION

Do not store in wet place. Keep away from light. Keep out of reach of children. (Mention any special pharmaceutical precautions recommended by the Product Development Department.)

PACKAGING

Farimab™ Solution for Injection:

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

SK+F BIOLOGICS
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
RUPGANJ, NARAYANGANJ, BANGLADESH
TM TRADEMARK
R/PM3600 V01

PM SPECIFICATION

Creative ID: CSD_04

Job Name: Farimab 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				