Prescribing information for Great Britain only.

▼ Vabysmo® (faricimab): 120mg/mL solution for injection. Single use vial containing 6mg faricimab / 0.05mL

Please refer to Summary of Product Characteristics (SPC) prior to use of Vabysmo. **Indications:** For the treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD) or visual impairment due to diabetic macular oedema (DMO). **Dose and Administration:** Vabysmo must be administered by a qualified healthcare professional trained in intravitreal injections. Always record batch number. *nAMD:* 6 mg (0.05 mL solution) administered by intravitreal injection under aseptic conditions every 4 weeks for the first 4 doses. Thereafter, treatment may be individualised using a treat-and-extend approach following an assessment of the individual patient's anatomic and visual outcomes. The dosing interval may be extended up to every 16 weeks, and extensions in increments of up to 4 weeks should be considered, based on the physician's judgement of the individual patient's anatomic and/or visual outcomes. If anatomic and/ or visual outcomes change, the treatment interval should be adjusted accordingly, and interval reductions of up to 8 weeks may be implemented if deemed necessary. Treatment intervals shorter than 21 days between injections have not been studied. *DMO:* 6 mg (0.05 mL solution) administered by intravitreal injection under aseptic conditions every 4 weeks for the first 4 doses. Thereafter, treatment may be individualised by using a treat- and extend approach following an assessment of the individual patient's anatomic and visual outcomes. Extend dosing intervals from every 4 to every 16 weeks, with extensions in increments of up to 4 weeks based on physician's judgement of anatomic and/or visual outcomes. If these change, the treatment interval should be adjusted accordingly and interval reductions of up to 8 weeks may be implemented. *nAMD and DMO:* Schedule monitoring between dosing based on patient status and at the physician's discretion. Vabysmo is intended for long-term treatment. Discontinue Vabysmo if visual and/or anatomic outcomes indicate no benefit. See SPC for instructions on method of administration. **Contraindications:** Ocular or periocular infections. Active intraocular inflammation. Hypersensitivity to faricimab or excipients. **Precautions:** Patients should report promptly any symptoms of intravitreal injection- related reactions. Vabysmo has not been studied in patients with poorly controlled glaucoma or in diabetic patients with uncontrolled hypertension. Exercise caution in patients with poorly controlled glaucoma. Monitor and manage intraocular pressure (IOP) and perfusion of the optic nerve head. Do not inject while IOP is ≥30 mmHg. Systemic adverse events including arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors, including Vabysmo. There is a potential for immunogenicity. Patients should inform their physician of any signs or symptoms of intraocular inflammation which might suggest hypersensitivity. Vabysmo administered in both eyes has not been studied. Exercise caution in patients with risk of retinal pigment epithelial tears. There is limited experience in the treatment of DMO patients with HbA1c over 10%, patients with high-risk proliferative diabetic retinopathy (DR), or nAMD and DMO patients with active systemic infections. Withhold treatment in patients with: rhegmatogenous retinal detachment, stage 3 or 4 macular holes, retinal break, treatment related decrease in Best Corrected Visual Acuity (BCVA) of ≥30 letters, performed or planned intraocular surgery within the previous or next 28 days. Do not administer concurrently with any other VEGF inhibitor. Women of childbearing potential should use effective contraception during and for at least 3 months following treatment. Avoid during pregnancy unless benefit outweighs the potential risk to the foetus. Vabysmo is not recommended during breast-feeding as risk to infant cannot be excluded. See SPC for details. Patients should not drive or use machines until visual function has recovered. **Adverse Events:** For more information, see SPC.

Very Common: cataract *Common:* conjunctival haemorrhage, vitreous detachment, vitreous floaters, retinal pigment epithelial tear (nAMD only), increased IOP, eye pain, increased lacrimation, corneal abrasion, eye irritation. *Serious:* uveitis, vitritis, endophthalmitis, retinal tear, rhegmatogenous retinal detachment, traumatic cataract.

Legal Category: POM. **NHS Costs:** 1 vial £857.

Marketing Authorisation Number:

Vabysmo is authorised in Great Britain - PLGB 00031/0927.

Supplied by: Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom.

Vabysmo is a registered trade mark.

Prescribing information for Northern Ireland only.

▼ Vabysmo® (faricimab): 120mg/mL solution for injection. Single use vial containing 6mg faricimab / 0.05mL

Please refer to Summary of Product Characteristics (SPC) prior to use of Vabysmo **Indications:** For the treatment of adult patients with neovascular (wet) age-related macular degeneration (nAMD) or visual impairment due to diabetic macular oedema (DMO). **Dose and Administration:** Vabysmo must be administered by a qualified physician experienced in intravitreal injections. Each vial should only be used for the treatment of a single eye. Always record batch number. *nAMD:* 6 mg (0.05 mL solution) administered by intravitreal injection under aseptic conditions every 4 weeks for the first 4 doses. Thereafter, an assessment of the disease activity based on anatomic and/or visual outcomes 20 and/or 24 weeks after treatment initiation is recommended. If no disease activity, consider treatment every 16 weeks. If disease activity, consider treatment every 8 or 12 weeks. *DMO:* 6 mg (0.05 mL solution) administered by intravitreal injection under aseptic conditions every 4 weeks for the first 4 doses. The dosing interval may be extended up to every 16 weeks (4 months), in increments of up to 4 weeks. If anatomic and/or visual outcomes change, the treatment interval should be adjusted accordingly. Treatment intervals shorter than 4 weeks between injections have not been studied. *nAMD and DMO:* Schedule monitoring between dosing based on patient status and at the physician's discretion. Vabysmo is intended for long-term treatment. Discontinue Vabysmo if visual and/or anatomic outcomes indicate no benefit. See SPC for instructions on method of administration.

Contraindications: Hypersensitivity to faricimab or excipients. Active or suspected ocular or periocular infections. Active intraocular inflammation.

Precautions: Patients should report promptly any symptoms of intravitreal injection-related reactions. Vabysmo has not been studied in patients with poorly controlled glaucoma or in diabetic patients with uncontrolled hypertension. Exercise caution in patients with poorly controlled glaucoma. Monitor and manage intraocular pressure (IOP) and perfusion of the optic nerve head. Do not inject while IOP is ≥30 mmHg. Systemic adverse events including arterial thromboembolic events have been reported following intravitreal injection of VEGF inhibitors, including Vabysmo. There is a potential for immunogenicity. Patients should inform their physician of any signs or symptoms of intraocular inflammation which might suggest hypersensitivity. Vabysmo administered in both eyes has not been studied. Exercise caution in patients with risk of retinal pigment epithelial tears. There is limited experience in the treatment of DMO patients with HbA1c over 10%, patients with high-risk proliferative diabetic retinopathy (DR), or nAMD and DMO patients with active systemic infections. Withhold treatment in patients with: rhegmatogenous retinal detachment, stage 3 or 4 macular holes, retinal break, treatment related decrease in Best Corrected Visual Acuity (BCVA) of ≥30 letters, subretinal haemorrhage involving the centre of the fovea, performed or planned intraocular surgery within the previous or next 28 days. Do not administer concurrently with any other VEGF inhibitor. Women of childbearing potential should use effective contraception during and for at least 3 months following treatment. Avoid during pregnancy unless benefit outweighs the potential risk to the foetus. Vabysmo is not recommended during breast- feeding as risk to infant cannot be excluded. See SPC for details. Patients should not drive or use machines until visual function has recovered.

Adverse Events: For more information, see SPC. *Very Common:* cataract *Common:* conjunctival haemorrhage, vitreous detachment, vitreous floaters, retinal pigment epithelial tear (nAMD only), IOP increased, eye pain, lacrimation increased, corneal abrasion, eye irritation. *Serious:* uveitis, endophthalmitis, vitritis, retinal tear, rhegmatogenous retinal detachment and traumatic cataract

Legal Category: POM. **NHS Costs:** 1 vial £857.

Marketing Authorisation Number:

Vabysmo is authorised in Northern Ireland - EU/1/22/1683/001

Supplied by: Roche Products Limited, 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom.

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▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554

As Vabysmo is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number

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