NOVARTIS

PAGENAX™ (brolucizumab)
120 mg/mL Solution for injection

Basic Succinct Statement (BSS)

Version 1.1

CODE: BSS RD 30 APR 2020; APPR 03 SEP 2020
This material is only meant for Healthcare Professionals

PAGENAX™

Important note: Before prescribing, consult full prescribing information.

Presentation: Solution for injection. Each vial contains 27.6 mg of brolucizumab in 0.23 mL solution.

Indications: Pagenax™ is indicated in adults for the treatment of neovascular (wet) age-related macular degeneration (AMD).

Dosage regimen and administration:

Single-use vial for intravitreal use only. Each vial should only be used for the treatment of a single eye. Pagenax must be administered by a qualified physician.

Adults: The recommended dose is 6 mg brolucizumab (0.05 ml solution) administered by intravitreal injection every 4 weeks (monthly) for the first 3 doses. Thereafter, the physician may individualise treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. In patients without disease activity, treatment every 12 weeks (3 months) should be considered. In patients with disease activity, treatment every 8 weeks (2 months) should be considered. The physician may further individualise treatment intervals based on disease activity.

Special populations: ♦Renal impairment: No dose adjustment is required. **♦Hepatic impairment:** No dose adjustment is required. **♦Geriatric patients:** No dose adjustment is required. **♦Pediatric patients:** Safety and efficacy have not been established.

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

Warnings and precautions: ♦Endophthalmitis, retinal detachment, retinal vasculitis and/or retinal vascular occlusion: Intravitreal injections, including those with Pagenax, have been associated with endophthalmitis and retinal detachment. Proper aseptic injection techniques must always be used when administering Pagenax. Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of Pagenax. Patients should be instructed to report any symptoms suggestive of the above mentioned events without delay. **♦Intraocular pressure increases:** Transient increases in intraocular pressure have been seen within 30 minutes of injection, similar to those observed with intravitreal administration of other VEGF inhibitors. Sustained intraocular pressure increases have also been reported. Both intraocular pressure and perfusion of the optic nerve head must be monitored and managed appropriately. **♦Driving and using machines:** Patients may experience temporary visual disturbances after an intravitreal injection with Pagenax and the associated eye examination. Advise patients not to drive or use machinery until visual function has recovered sufficiently.

Pregnancy, lactation, females and males of reproductive potential

Pregnancy: The potential risk of use of Pagenax in pregnancy is unknown. However, based on the anti-VEGF mechanism of action, brolucizumab must be regarded as potentially teratogenic

and embryo/fetotoxic. Therefore, Pagenax should not be used during pregnancy unless the expected benefits outweighs the potential risks to the fetus.

Lactation: Breast-feeding is not recommended during treatment and for at least one month after the last dose when stopping treatment with Pagenax.

Females and males of reproductive potential: Women of reproductive potential should use effective contraception (methods that result in less than 1% pregnancy rates) during treatment with Pagenax and for at least one month after the last dose when stopping treatment with Pagenax.

Adverse drug reactions:

From clinical studies:

♦ **Common (1 to 10%):** Visual acuity reduced, retinal haemorrhage, uveitis, iritis, vitreous detachment, retinal tear, cataracts, conjunctival haemorrhage, vitreous floaters, eye pain, intraocular pressure increase, conjunctivitis, retinal pigment epithelial tear, vision blurred, corneal abrasion, punctate keratitis, hypersensitivity.

♦ **Uncommon (<1%):** Endophthalmitis, blindness, retinal artery occlusion, retinal detachment, conjunctival hyperaemia, lacrimation increased, abnormal sensation in eye, detachment of retinal pigment epithelium, vitritis, anterior chamber inflammation, irirodyclitis, anterior chamber flare, corneal oedema, vitreous haemorrhage.

From spontaneous reports and literature:

♦ **Frequency not known:** Retinal vasculitis, retinal vascular occlusion.

Interactions: No formal interaction studies have been performed.