NOVARTIS

ACCENTRIX® (ranibizumab)

10 mg/mL solution for injection

Basic Succinct Statement

Version 3.2

Code: BSS RD 04 Dec 18; APPR 02 Nov 20

This material is only meant for Healthcare Professionals

ACCENTRIX®

Note: Before prescribing, consult full prescribing information.

Presentation: **Vial**: Ranibizumab. Each vial contains 2.3 mg of ranibizumab in 0.23 mL solution.

Indications: ♦Treatment of neovascular (wet) age-related macular degeneration (AMD). ♦Treatment of visual impairment due to diabetic macular edema (DME). ♦Treatment of proliferative diabetic retinopathy (PDR). ♦Treatment of visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO). ♦Treatment of visual impairment due to choroidal neovascularization (CNV).

Dosage and administration: ♦The recommended dose for Accentrix is 0.5 mg (0.05mL) given as a single intravitreal injection. The interval between two doses injected into the same eye should be at least four weeks. ♦Treatment is initiated with one injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity. In patients with wet AMD, DME, PDR and RVO, initially, three or more consecutive, monthly injections may be needed. ♦Thereafter, monitoring and treatment intervals should be determined by the physician and should be based on disease activity as assessed by visual acuity and/or anatomical parameters. ♦If, in the physician's opinion, visual and anatomic parameters indicate that the patient is not benefiting from continued treatment, Accentrix should be discontinued. ♦Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (e.g. optical coherence tomography or fluorescein angiography). ♦While applying the treat-and-extend regimen, the treatment interval should be extended by two weeks at a time for wet AMD or by one month at a time for DME. For PDR and RVO, treatment intervals may be gradually extended, however there are insufficient data to conclude on the length of these intervals. If disease activity recurs, the treatment interval should be shortened accordingly. ♦The treatment of visual impairment due to CNV should be determined individually per patient based on disease activity. Some patients may need one injection during the first 12 months; others may need more frequent treatment, including a monthly injection. For CNV secondary to pathologic myopia (PM), many patients may need one or two injections during the first year, while some patients may need more frequent treatment. ♦**Accentrix and laser photocoagulation in DME or in branch RVO**: Accentrix has been used concomitantly with laser photocoagulation in clinical studies. When given on the same day, Accentrix should be administered at least 30 minutes after laser photocoagulation. Accentrix can be administered in patients who have received previous laser photocoagulation. ♦ Accentrix must be administered by a qualified ophthalmologist using aseptic techniques. Broad-spectrum topical microbicide and anaesthetic should be administered prior to the injection. ♦Not recommended in children and adolescents.

Contraindications: Hypersensitivity to ranibizumab or to any of the excipients, patients with active or suspected ocular or periocular infections, patients with active intraocular inflammation.

Warnings and Precautions: ♦ Intravitreal injections have been associated with endophthalmitis, intraocular inflammation, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract. Therefore proper aseptic injection techniques must be used.

Patients should be monitored during the week following the injection to permit early treatment if an infection occurs. ♦Transient increases in intraocular pressure (IOP) have been seen within 60 minutes of injection of Accentrix. Sustained IOP increases have also been reported. Intraocular pressure and the perfusion of the optic nerve head must be monitored and managed appropriately. ♦There is a potential risk of arterial thromboembolic events following intravitreal use of VEGF inhibitors. A numerically higher stroke rate was observed in patients treated with Accentrix 0.5 mg compared to Accentrix 0.3 mg or control; however, the differences were not statistically significant. Patients with known risk factors for stroke, including history of prior stroke or transient ischemic attack should be carefully evaluated by their physicians as to whether Accentrix treatment is appropriate and the benefit outweighs the potential risk. ♦Available data do not suggest an increased risk of systemic adverse events with bilateral treatment. ♦As with all therapeutic proteins, there is a potential for immunogenicity with Accentrix. ♦Accentrix has not been studied in patients with active systemic infections or in patients with concurrent eye conditions such as retinal detachment or macular hole. ♦Should not be used during pregnancy unless the expected benefit outweighs the potential risk to the fetus. For women who wish to become pregnant and have been treated with Accentrix, it is recommended to wait at least 3 months after the last dose of Accentrix before conceiving a child; use of effective contraception is recommended for women of child-bearing potential; breast-feeding is not recommended. ♦Following treatment patients may develop transient visual disturbances that may interfere with their ability to drive or use machines. Patients should not drive or use machines as long as these symptoms persist.

Adverse drug reactions: ♦ **Very common (≥10%):** intraocular inflammation, vitritis, vitreous detachment, retinal hemorrhage, visual disturbance, eye pain, vitreous floaters, conjunctival hemorrhage, eye irritation, foreign body sensation in eyes, lacrimation increased, blepharitis, dry eye, ocular hyperemia, eye pruritus, intraocular pressure increased, nasopharyngitis, headache, arthralgia. ♦**Common (1 to 10%):** retinal degeneration, retinal disorder, retinal detachment, retinal tear, detachment of the retinal pigment epithelium, retinal pigment epithelium tear, visual acuity reduced, vitreous hemorrhage, vitreous disorder, uveitis, iritis, iridocyclitis, cataract, cataract subcapsular, posterior capsule opacification, punctuate keratitis, corneal abrasion, anterior chamber flare, vision blurred, injection site hemorrhage, eye hemorrhage, conjunctivitis, conjunctivitis allergic, eye discharge, photopsia, photophobia, ocular discomfort, eyelid edema, eyelid pain, conjunctival hyperemia, stroke, influenza, urinary tract infection*, anemia, anxiety, cough, nausea, allergic reactions (rash, pruritus, urticaria, erythema). ♦**Uncommon (0.1 to 1%) :** blindness, endophthalmitis, hypopyon, hyphema, keratopathy, iris adhesions, corneal deposits, corneal edema, corneal striae, injection site pain, injection site irritation, abnormal sensation in eye, eyelid irritation. ♦**Serious adverse events** related to intravitreal injections include endophthalmitis, rhegmatogenous retinal detachment, retinal tear and iatrogenic traumatic cataract.

** observed only in the DME population*