NEW INDICATION

OZURDEX® (dexamethasone intravitreal implant): For the treatment of adult patients with visual impairment due to diabetic macular edema (DME) who are considered unsuitable for, or insufficiently responsive to, non-corticosteroid therapy or are pseudophakic.

Presentation:
Disposable intravitreal implant. The implant consists of a rod-shaped drug delivery device, containing a dexamethasone implant which is not visible. The implant is approximately 0.46 mm in diameter and 6 mm in length.

Indications:
- Treatment of adult patients with diabetic macular edema
- Treatment of adult patients with macular edema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO)
- Treatment of posterior segment of the eye presenting as non-infectious uveitis and visual impairment due to diabetic macular edema
- Treatment of posterior segment of the eye presenting as non-infectious uveitis and visual impairment due to diabetic macular edema
- Treatment of posterior segment of the eye presenting as non-infectious uveitis and visual impairment due to ocular herpes simplex
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- Treatment of posterior segment of the eye presenting as non-infectious uveitis and visual impairment due to ocular herpes simplex

Contraindications:
- Hypersensitivity to the active substance or to any of the excipients
- Active or suspected ocular or periocular infections
- Advanced glaucoma which cannot be adequately controlled by medicinal products alone
- Aphakic eyes with posterior capsule tear, such as those with a posterior lens (e.g. due to cataract surgery), and/or those with a history of vitrectomy, are at risk of implant migration into the anterior chamber. Implant migration to the anterior chamber may lead to visual impairment
- Persistent severe corneal edema could progress to the need for corneal transplantation
- Other than those patients contraindicated where OZURDEX should not be used

Dosage and Administration:
- The recommended dose is one OZURDEX implant

Adverse reactions:
- Very Common (≥ 1/10): IOP increased, cataract, conjunctival hyperemia, subepithelial opacities
- Common (≥1/100 to <1/10): headache, ocular hypertension, cataract subcapsular, vitreous haemorrhage

Use of Machines:
Patients may experience temporarily reduced vision after receiving OZURDEX by intravitreal injection. They should not drive or use machines until this has resolved.

Legal Category:
NICE classification. OZURDEX must be administered by a qualified ophthalmologist experienced in intravitreal injections. The recommender dose is one OZURDEX implant to be administered intravitreally to the affected eye. Administration to both eyes consecutively is not recommended. Repeat doses should be considered when a patient experiences a response to treatment followed subsequently by a loss in visual acuity and in the physician’s opinion may benefit from removal without being exposed to its risk. Patients who experience and retain improved vision should not be retreated. Patients who experience a deterioration in vision, which is not shown by OZURDEX, should not be retreated. In BRVO and CRVO there is only very limited information on repeat dosage with intervals less than 6 months. There is currently no experience of repeat administrations in posterior segment non-infectious uveitis with more than 2 implants in Branch Retinal Vein Occlusion. In DME there is no experience of repeat administrations beyond 7 implants. Patients should be examined following the injection to permit early treatment if an infection or increased intraocular pressure occurs. Single- or multiple-implant injection should be carried out under controlled conditions as described in the Summary of Product Characteristics. The patient should be instructed to self-administer fixed spectrum corticosteroid drops daily for 3 days before and after each injection.


Date of preparation: September 2014

OZURDEX (Dexamethasone 700 micrograms intravitreal implant in applicator)

OZURDEX® (Dexamethasone 700 micrograms intravitreal implant in applicator)

Presentation:
Disposable intravitreal implant. One implant contains 700 micrograms of dexamethasone. Disposable applicator device, containing a dexamethasone implant which is not visible. The implant is approximately 0.46 mm in diameter and 6 mm in length.

Indications:
- Treatment of adult patients with diabetic macular edema
- Treatment of adult patients with macular edema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO)
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Contraindications:
- Hypersensitivity to the active substance or to any of the excipients
- Active or suspected ocular or periocular infections
- Advanced glaucoma which cannot be adequately controlled by medicinal products alone
- Aphakic eyes with posterior capsule tear, such as those with a posterior lens (e.g. due to cataract surgery), and/or those with a history of vitrectomy, are at risk of implant migration into the anterior chamber. Implant migration to the anterior chamber may lead to visual impairment
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**LUCENTIS® for treatment of:**

- Neovascular (wet) age-related macular degeneration (AMD).
- Visual impairment due to diabetic macular edema (DME).
- Visual impairment due to macular edema secondary to retinal vein occlusion (branch RVO or central RVO).
- Visual impairment due to choroidal neovascularisation (CNV) secondary to pathologic myopia (PM).

**Note:** Before prescribing, consult full prescribing information.

**Presentation:** Vial: Ranibizumab. Each vial contains 2.3 mg of ranibizumab in 0.23 mL solution. Pre-filled syringe: Ranibizumab. Each pre-filled syringe contains 0.64 mg of ranibizumab in 0.165 mL solution.

**Indications:**
- Treatment of neovascular (wet) age-related macular degeneration (AMD).
- Treatment of visual impairment due to diabetic macular edema (DME).
- 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 neovascularisation (CNV) secondary to pathologic myopia (PM).

**Dosage and administration:**
- The recommended dose is 0.5 mg (0.05 mL) given as a single intravitreal injection.
- Treatment is initiated with one injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity.
- Monitoring and treatment intervals should be determined by the physician and should be based on disease activity as assessed by visual acuity and/or anatomic parameters.
- 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 and central RVO, or by one month at a time for DME and branch RVO.
- Lucentis and laser photocoagulation in DME or in branch RVO: Lucentis has been used concomitantly with laser photocoagulation in clinical studies. When given on the same day, Lucentis should be administered prior to the injection.
- Treatment is not recommended. 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 ranibizumab, it is recommended to wait at least 3 months after the last dose of ranibizumab before conceiving a child; use of effective contraception is recommended for women of child-bearing potential; breastfeeding 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.

**Interactions:**
No formal interaction studies have been performed.

**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 keratites, 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, endotheliitis, hypopyon, hyphaema, 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.

**Pack and prices:** Country-specific.

**Legal classification:** Country-specific.

See your success in the eyes of your patients

Novartis indications may vary from country to country. Physicians should refer to their National Prescribing Information.

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