PRESCRIBING INFORMATION (PI)

OZURDEX© (dexamethasone) 700 micrograms intravitreal implant in applicator
Refer to Summary of Product Characteristics (SmPC) before prescribing.

PRESENTATION: Intravitreal implant in applicator. One implant contains 700 micrograms of dexamethasone. Disposable injection device, containing a rod-shaped 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 macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO), inflammation of the posterior segment of the eye presenting as non-infectious uveitis and visual impairment due to diabetic macular oedema (DME) who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy. **DOSAGE AND ADMINISTRATION:** OZURDEX must be administered by a qualified healthcare professional experienced in intravitreal injections. **Posology:** The recommended dose is one OZURDEX implant to be administered intra-vitreally to the affected eye. Administration to both eyes concurrently is not recommended. *DME:* Patients treated with OZURDEX who have experienced an initial response and in the physician's opinion may benefit from retreatment without being exposed to significant risk should be considered for retreatment. Retreatment may be performed after approximately 6 months if the patient experiences decreased vision and/or an increase in retinal thickness, secondary to recurrent or worsening diabetic macular oedema. There is no experience of repeat administration beyond 7 implants. *RVO and uveitis:* 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 retreatment without being exposed to significant risk. Patients who experience and retain improved vision should not be retreated. Patients who experience a deterioration in vision, which is not slowed by OZURDEX, should not be retreated. There is only very limited information on repeat dosing intervals less than 6 months. Patients should be monitored following the injection to permit early treatment if an infection or increased intraocular pressure occurs. There is currently no experience of repeat administrations in posterior segment non-infectious uveitis or beyond 2 implants in Retinal Vein Occlusion. **Special Populations:** *Elderly:* No dose adjustment is required for elderly patients. *Renal and/or Hepatic impairment:* OZURDEX has not been studied in patients with renal and/or hepatic impairment however no special considerations are needed in this population. *Paediatric population:* The safety and efficacy of OZURDEX in the paediatric population have not been established. No data are available. **Method of Administration:** Single-use intravitreal implant in applicator for intravitreal use only. The intravitreal injection procedure should be carried out under controlled aseptic conditions as described in the Summary of Product Characteristics. The patient should be instructed to self-administer broad spectrum antimicrobial drops daily for 3 days before and after each injection. For instructions on the administration of the intravitreal implant, see SmPC. **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. Active or suspected ocular or periocular infection including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases. Advanced glaucoma which cannot be adequately controlled by medicinal products alone. Aphakic eyes with ruptured posterior lens capsule. Eyes with Anterior Chamber Intraocular Lens (ACIOL), iris or transscleral fixated intraocular lens and ruptured posterior lens capsule. **SPECIAL WARNINGS AND PRECAUTIONS:** Intravitreous injections, including OZURDEX can be associated with endophthalmitis, intraocular inflammation, increased intraocular pressure and retinal detachment. Proper aseptic injection techniques must always be used. Patients should be monitored following the injection to permit early treatment if an infection or increased intraocular pressure occurs. Monitoring may consist of a check for perfusion of the optic nerve head immediately after the injection, tonometry within 30 minutes following the injection, and biomicroscopy between two and seven days following the injection. Patients must be instructed to report any symptoms suggestive of endophthalmitis or any of the above-mentioned events without delay. All patients with posterior capsule tear, such as those with a posterior lens (e.g. due to cataract surgery), and/or those who have an iris opening to the vitreous cavity (e.g. due to iridectomy) with or without a history of vitrectomy, are at risk of implant migration into the anterior chamber. Implant migration to the anterior chamber may lead to corneal oedema. Persistent severe corneal oedema could progress to the need for corneal transplantation. Other than those patients contraindicated where OZURDEX should not be used, OZURDEX should be used with caution and only following a careful risk benefit assessment. These patients should be closely monitored to allow for early diagnosis and management of device migration. Use of corticosteroids, including OZURDEX, may induce cataracts (including posterior subcapsular cataracts), increased IOP, steroid induced glaucoma and may result in secondary ocular infections. As expected with ocular steroid treatment and intravitreal injections, increases in intraocular pressure (IOP) may be seen. The rise in IOP is normally manageable with IOP lowering medication. Corticosteroids should be used cautiously in patients with a history of ocular viral infection and not be used in active ocular herpes simplex. OZURDEX is not recommended in patients with macular oedema secondary to RVO with significant retinal ischemia. OZURDEX should be used with caution in patients taking anti-coagulant or anti-platelet medicinal products. OZURDEX administration to both eyes concurrently is not recommended. Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, consider evaluating for possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids. **INTERACTIONS:** No interaction studies have been performed. Systemic absorption is minimal, and no interactions are anticipated. **FERTILITY, PREGNANCY AND LACTATION:** *Pregnancy:* Studies in animals have shown teratogenic effects following topical ophthalmic administration. There are no adequate data from the use of intravitreally administered dexamethasone in pregnant women. Long-term systemic treatment with glucocorticoids during pregnancy increases the risk for intra-uterine growth retardation and adrenal insufficiency of the newborn child. Therefore, although the systemic exposure of dexamethasone would be expected to be very low after local, intraocular treatment, OZURDEX is not recommended during pregnancy unless the potential benefit justifies the potential risk to the foetus. *Breast-feeding:* Dexamethasone is excreted in breast milk. No effects on the child are anticipated due to the route of administration and the resulting systemic levels. However, OZURDEX is not recommended during breast-feeding unless clearly necessary. *Fertility:* There are no fertility data available. **ABILITY TO DRIVE AND USE MACHINES:** Patients may experience temporarily reduced vision after receiving OZURDEX by intravitreal injection. They should not drive or use machines until this has resolved. **UNDESIRABLE EFFECTS:** See SmPC for full list of adverse events. In clinical trials the most frequently reported adverse events were increased intraocular pressure (IOP), cataract and conjunctival haemorrhage. Increased IOP with OZURDEX peaked at day 60 and returned to baseline levels by day 180. With the exception of headache and migraine, no systemic adverse drug reactions were identified with the use of OZURDEX. The following adverse events were reported: **Serious:** cataract, cataract subcapsular, necrotizing retinitis, endophthalmitis, retinal detachment, retinal tear, vitreous haemorrhage, conjunctival haemorrhage. **Very Common (≥ 1/10):** IOP increased, cataract, conjunctival haemorrhage. **Common (≥1/100 to <1/10):** headache, ocular hypertension, cataract subcapsular, vitreous haemorrhage, visual acuity reduced, visual impairment/disturbance, vitreous detachment, vitreous floaters, vitreous opacities, blepharitis, eye pain, photopsia, conjunctival oedema, conjunctival hyperaemia. **MARKETING AUTHORISATION NUMBERS/PRESENTATION/NHS LIST PRICE:** Great Britain (**GB**) PLGB 41042/0085, £870 per pack containing 1 implant. **LEGAL CLASSIFICATION:** POM **MA HOLDER:** Further information available from Abbvie Ltd, Maidenhead, SL6 4UB. **DATE OF REVISION:** November 2023 **DOCUMENT NUMBER:** OZDX-UK-00001-C

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or via the MHRA Yellow Card app, available in the Google Play or Apple App Stores. Adverse events should also be reported to AbbVie on GBPV@abbvie.com