INVITATION

ABBVIE RETINA STANDALONE

CEExperience RETINA

30th NOVEMBER 2024 at 9:30

RADISSON BLU PLAZA HOTEL, BRATISLAVSKA 8, LJUBLJANA, SLOVENIA

AGENDA:

9:30 – 10:00	**REGISTRATION**
Morning lectures:	
10:00 – 10:15	**Introduction** AbbVie & Moderators, Borna Šarić, Croatia, Polona Jaki Mekjavić, Slovenia
10:15 – 10:50	**Current unmet needs in DME** Anat Loewenstein, Izrael VIRTUAL ATTENDANCE
10:50 – 11:05	**Inflammation in DME & RVO** Dijana Risimić, Serbia
11:05 - 11:20	**MoA of steroids in DME & RVO** Ewa Fluder, Poland
11:20 – 11:35	**Diagnosis and OCT findings & Biomarkers** Marija Štanfel, Croatia
11:35 – 11:50	**DME Consensuses & Algorithms** Mojca Urbančič, Slovenia
11:50 – 12:05	**Naive patients with DME & Ozurdex** Jurate Vilma Balciuniene, Lithuania
12:05 – 12:15	**Closing of lectures** Moderators: Borna Šarić, Croatia, Polona Jaki Mekjavić, Slovenia
12:15 – 13:30	**LUNCH**
13:30 – 15:30	**INTERACTIVE WORKSHOPS**

Uveitis - Workshop 1

Nataša Vidović Valentinčič, Slovenia (30')

DME - Workshop 2

Vlatka Brzović Šarić, Croatia (30')

RVO - Workshop 3

Ivana Gardašević Topčić, Slovenia (30')

Ozurdex Injection Training

Borna Šarić, Croatia
Mojca Urbančič, Slovenia (30')

Participants will be divided in smaller groups and they will rotate between the workshops.

The event will take place on Saturday, **30th November 2024 at 9:30 AM,** at Radisson Blu Plaza Hotel, Bratislavska cesta 8, Ljubljana, Slovenia.

Please, confirm your attendance **until 20th November 2024** to your local representative:

Baltics: donatas.papeika@abbvie.com

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We are looking forward to seeing you at the event!

Kind regards,

AbbVie Team

ABBREVIATED SUMMARY OF PRODUCT CHARACTERISTICS

OZURDEX 700 micrograms intravitreal implant in applicator

Qualitative and quantitative composition: One implant contains 700 micrograms of dexamethasone. **Therapeutic indications:** OZURDEX is indicated for the treatment of adult patients with: visual impairment due to diabetic macular oedema (DME) who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy; 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. **Posology and method of administration:** OZURDEX must be administered by a qualified ophthalmologist 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 currently no experience of the efficacy or safety of repeat administrations in DME 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 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. For information concerning the current safety experience of repeat administrations beyond 2 implants in posterior segment non-infectious uveitis and Retinal Vein Occlusion, see section 4.8 of SmPC. *Special populations: Elderly (≥ 65 år):* No dose adjustment is required for elderly patients. *Renal and hepatic impairment:* OZURDEX has not been studied in patients with renal or hepatic impairment however no special considerations are needed in this population. *Paediatric population:* There is no relevant use of OZURDEX in the paediatric population in: diabetic macular oedema and macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO). The safety and efficacy of OZURDEX in uveitis in the paediatric population have not been established. Method of administration: OZURDEX is a single-use intravitreal implant in applicator for intravitreal use only. Each applicator can only be used for the treatment of a single eye. The intravitreal injection procedure should be carried out under controlled aseptic conditions which include the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). The patient should be instructed to self-administer broad spectrum antimicrobial drops daily for 3 days before and after each injection. Before the injection, the periocular skin, eyelid and ocular surface should be disinfected (using for example drops of povidone iodine 5% solution on the conjunctiva as it was done in the clinical trials for the approval of OZURDEX) and adequate local anaesthesia should be administered. Remove the foil pouch from the carton and examine for damage. Then, in a sterile field, open the foil pouch and gently place the applicator on a sterile tray. Carefully remove the cap from the applicator. Once the foil pouch is opened the applicator should be used immediately. Hold the applicator in one hand and pull the safety tab straight off the applicator. Do not twist or flex the tab. With the bevel of the needle up away from the sclera, advance the needle about 1 mm into the sclera then redirect toward the centre of the eye into the vitreous cavity until the silicone sleeve is against the conjunctiva. Slowly press the actuator button until an audible click is noted. Before withdrawing the applicator from the eye, make sure that the actuator button is fully pressed and has locked flush with the applicator surface. Remove the needle in the same direction as used to enter the vitreous. Immediately after injecting OZURDEX, use indirect ophthalmoscopy in the quadrant of injection to confirm successful implantation. Visualisation is possible in the large majority of cases. In cases in which the implant cannot be visualised, take a sterile cotton bud and lightly depress over the injection site to bring the implant into view. Following the intravitreal injection patients should continue to be treated with a broad spectrum antimicrobial. **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. **Summary of special warnings and precautions for use:** Intravitreous injections 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. Patients must be instructed to report any symptoms suggestive of endophthalmitis or any of the above mentioned events. 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 may induce cataracts (including posterior subcapsular cataracts), increased IOP, steroid induced glaucoma and may result in secondary ocular infections. Corticosteroids should be used cautiously in patients with a history of ocular viral (e.g. herpes simplex) infection and not be used in active ocular herpes simplex. OZURDEX has not been studied in patients with macular oedema secondary to RVO with significant retinal ischemia. Therefore OZURDEX is not recommended. OZURDEX should be used with caution in patients taking anti-coagulant or anti-platelet medicinal products. **Interaction with other medicinal products and other forms of interaction:** Systemic absorption is minimal and no interactions are anticipated. **Fertility, pregnancy and lactation:** Pregnancy: 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. **Effects on ability to drive and use machines:** OZURDEX may have a moderate influence on the 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:** Very common: intraocular pressure increased, cataract, conjunctival haemorrhage. Common: 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. Uncommon: migraine, necrotizing retinitis, endophthalmitis, glaucoma, retinal detachment, retinal tear, hypotony of the eye, anterior chamber inflammation, anterior chamber cells/flares, abnormal sensation in eye, eyelids pruritus, scleral hyperaemia, device dislocation (migration of implant) with or without corneal oedema; complication of device insertion resulting in ocular tissue injury (implant misplacement). **Marketing authorisation holder:** AbbVie Deutschland GmbH & Co. KG, Knollstrasse, 67061 Ludwigshafen, Germany. **Classification for supply:** ZZ - Medicinal products prescribed and dispensed to medical prescription, which shall be used in public health institutions only and by legal entities and natural persons pursuing healthcare services. **Please read the full Summary of Product Characteristics (SmPC) before prescribing and using OZURDEX. Date of revision:** 06/2024.

abbvie

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Ozurdex®
(dexamethasone intravitreal implant) 0.7mg

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