

# INFORMED CONSENT FOR PERIOCLAR REPOSITORY CORTICOSTEROID INJECTION(S) - PRCI

## INDICATIONS AND POSSIBLE BENEFITS

Your eye doctor (ophthalmologist) has diagnosed you with an eye condition that causes swelling, leakage from the blood vessels in the eye, inflammation and/or the abnormal growth of blood vessels. Triamcinolone acetonide (Kenalog™) and Methylprednisalone (DepoMedrol™) are steroid medications which can be injected into the soft tissues around and behind the eye. This type of injection is called Periocular Repository Corticosteroid Injection (PRCI). This kind of injection can reduce the swelling, leakage, inflammation and abnormal blood vessel growth, and may improve how well you see or prevent additional visual loss.

## “OFF-LABEL” STATUS INFORMATION

Kenalog,™ and DepoMedrol™ are approved to treat the swelling caused by many medical conditions, but are not approved for use in the eye. The use of a medication for an “off-label” purpose is a legal and necessary part of the practice of medicine. The FDA has confirmed that once it approves a medication, physicians may use it “off-label” for other purposes if that use will benefit their patient. Kenalog,™ and DepoMedrol™ are in wide use for treating eye conditions. Dr. Alldredge feels that the “off-label” use of this medication is needed to treat your eye condition at this time.

## POSSIBLE LIMITATIONS

The goal of treatment with PRCI is to prevent further loss of vision. Although some patients have regained vision, the medication may not restore vision that has already been lost, and may not ultimately prevent further loss of vision caused by your disease.

## ADMINISTRATION

The eye is numbed with anesthetic eye drops, the medication is injected into the soft tissue next to eye, the jelly-like substance in the back part of the eye. IVTA is administered by an injection into your eye as needed; your ophthalmologist will tell you how often you will receive the injection, and for how long.

## ALTERNATIVES

You do not have to receive PRCI treatment for your condition, although without treatment, diseases like yours can lead to further vision loss and blindness, sometimes very quickly.

## COMPLICATIONS FROM THE MEDICATION AND INJECTION

Your condition may not get better or it may become worse. Any or all of these complications discussed below may cause you to lose vision or cause blindness. Additional medications or procedures, including surgery, may be needed to treat these complications. During the follow up visits, you will be checked for possible side effects and the results will be discussed with you.

Possible complications and side effects of PRCI include but are not limited to Inadvertent injection into the choroidal or retinal circulation, emboli, perforation of the eye with permanent loss of vision/loss of eye, cataract, glaucoma (increased eye pressure) that may be transient or permanent and could lead to medical or surgical treatment (i.e., excision of depot or glaucoma operation, blepharoptosis, proptosis, orbital fat atrophy, fibrosis, delayed hypersensitivity reactions, strabismus, conjunctival hemorrhage, chemosis, infection, pain from injection, syncope, adhesions, worsening of condition, Cushing’s Syndrome, pupillary dilatation. Any of these rare complications may lead to severe, permanent loss of vision.

Patient Initials \_\_\_\_\_  
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Patients receiving PRCI may experience less severe side effects related to the pre-injection preparation procedure (anesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anesthetic). These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances.

**PATIENT CONSENT:**

The above explanation has been read by/to me. The nature of my eye condition has been explained to me and the proposed treatment has been described. The risks, benefits, alternatives, and limitations of the treatment have been discussed with me. All of my questions have been answered.

- I understand that Kenalog™ and DepoMedrol™ were approved by the FDA for injections into muscles, the skin, and joints, and that it has not been approved for injection in or around the eye to treat eye conditions. Nevertheless, I wish to be treated with Kenalog™ and/or DepoMedrol™ and I am willing to accept the potential risks that my physician has discussed with me.
- I will take all prescribed medications exactly as ordered and will immediately contact my ophthalmologist if any of the following signs of infection or other complications develop: pain, blurry or decreased vision, sensitivity to light, redness of the eye (compared to immediately after the injection), or discharge from the eye. I will keep all post-injection appointments so my doctor can check for complications.
- I hereby authorize Dr. Claron D. Alldredge to administer Periocular Repository Corticosteroid Injection (PRCI) of Kenalog™ and/or DepoMedrol™ as needed. This consent will be valid unless I revoke it by refusing an injection or my condition changes to the point that the risks and benefits of this medication for me are significantly different.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date