

INFORMED CONSENT FOR INTRAVITREAL INJECTION OF TRIAMCINOLONE ACETONIDE OR KENALOG (IVTA)

INDICATIONS AND POSSIBLE BENEFITS

Your eye doctor (ophthalmologist) has diagnosed you with an eye condition that causes swelling (edema or inflammation), leakage from the blood vessels in the eye, and/or the abnormal growth of blood vessels. Triamcinolone acetonide (TA) is a steroid injected into the jelly or vitreous portion of the eye; we will refer to this type of injection of this drug as IVTA. IVTA reduces the swelling, leakage, and abnormal blood vessel growth, and may improve how well you see.

“OFF-LABEL” STATUS INFORMATION

Triamcinolone acetonide is approved to treat the swelling caused by many medical conditions, but is not approved for use in the eye. Kenalog™ must be withdrawn from a vial and placed into a syringe. 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. Before doing so, ophthalmologists are expected to know the medication well and have sound medical evidence for its use. Your ophthalmologist feels that the “off-label” use of this medication is needed to treat your eye condition at this time.

POSSIBLE LIMITATIONS AND ADMINISTRATION

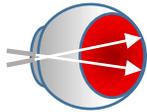
The goal of treatment with IVTA is to prevent further loss of vision. Although some patients have regained vision, the medication may not restore vision that has already been lost, and may not ultimately prevent further loss of vision caused by your disease. After the pupil is dilated and the eye is numbed with anesthesia, the medication is injected into the vitreous, 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 TA treatment for your condition, although without treatment, diseases like yours can lead to further vision loss and blindness, sometimes very quickly. Your ophthalmologist will let you know if other medications are available for your condition, whether laser or other types of surgery are the only alternatives, and whether these treatments have already been tried but have not helped your condition.

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 or phone calls, you will be checked for possible side effects and the results will be discussed with you.



Possible complications and side effects of IVTA include but are not limited to

- retinal detachment,
- cataract formation (clouding of the lens of the eye),
- glaucoma (increased pressure in the eye),
- hypotony (reduced pressure in the eye),
- damage to the retina or cornea (structures of the eye),
- bleeding,
- eye infection (endophthalmitis),
- any of these rare complications may lead to severe, permanent loss of vision or loss of eye.

Patients receiving IVTA may experience less severe side effects related to the pre-injection preparation procedure (eyelid speculum, 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.

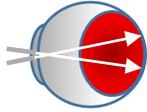
PATIENT CONSENT:

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™ was 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. I understand that two other forms of the same medication, known as Triesence™ and Trivaris™ have been approved for eye conditions. Nevertheless, I wish to be treated with Kenalog™, 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 have been instructed NOT to rub my eyes or swim for three days after each injection. I will keep all post-injection appointments or scheduled telephone calls so my doctor can check for complications.
- I hereby authorize Dr. Peddada to administer the intravitreal injection of TA in my "right" / "left" eye at regular intervals 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



WHAT TO EXPECT AFTER YOUR INJECTION

- Immediately after your injection you will see floaters or black spots. This is the medication or air bubbles inside of the eye.
- Your vision may remain blurry for a few days.
- You may experience mild discomfort in your eye after the treatment. Keeping your eye closed or using artificial tears will help lessen any tearing or discomfort. Your eye should feel better within 24-48 hours after the procedure.
- Your eye may be red at the injection site or you may have a hemorrhage under the outer membrane of the eye (on the white part of the eye.) This is common and not considered a complication. This may take a few days to go away.

OTHER INSTRUCTIONS

- Do not wear eye makeup, contact lens or swim for 3 days.
- If the eye becomes light sensitive, painful or a decrease in vision occurs, please call our office immediately at (334) 521-0041 or (706) 221-9702.
- Leave the patch on the eye till the next morning.
- Do not splash water on face or hair for 4 days (use a cloth to wash your face).
- DO NOT RUB THE EYE!!