This form is intended as a sample. It does not constitute the standard of care nor does it provide legal advice. It contains the information OMIC recommends the physician personally discuss with the patient.

**How to use this sample**

* Please modify it to fit your actual practice.
* **Remove this instruction box.**
* Add your letterhead to the first page of the consent form.
* Change font size if necessary.

**After the patient signs the form**

* Give the patient a copy of the signed form.
* Send a copy to the hospital or surgery center as verification that you have obtained informed consent.
* Keep the original in the patient’s medical record.

**Version** 3/20/23

 **[Your Letterhead]**

**Informed Consent for Xipere® (triamcinolone acetonide injectable suspension)**

**How Xipere® treats your condition**

Your ophthalmologist has diagnosed you with an eye condition that causes swelling and inflammation of the eye. Xipere® (triamcinolone acetonide) is a steroid medication that is injected into the eye to treat swelling and inflammation, and may improve how well you see.

**Benefits (how this medication can help)**

The goal of treatment with Xipere® is to prevent further vision loss. 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.

**How the injection is given**

After the eye is numbed with anesthesia, the ophthalmologist will inject the medication into the suprachoroidal space (the area between the retina and the white part of your eye). Your ophthalmologist will tell you how often and for how long you need to receive it.

**Tell your ophthalmologist about all the medicines you take**, including prescription and over the counter medicines, vitamins, and herbal supplements.

**Tell your ophthalmologist right away if you notice any problems after the injection, such as:**

* Signs of infection, which include eye pain, blurry or decreased vision, being extra sensitive to light, eye redness, and pus or other discharge coming from the eye.

**You must follow these instructions:**

• Do not rub your eyes or go swimming for 3 days after each injection.

• Call your ophthalmologist right away if you notice any of the problems listed above.

• Keep all appointments with your ophthalmologist.

**Contact your primary care physician or go to the emergency room if you experience rare, but serious, complications that could affect other organs, including abdominal pain associated with constipation and vomiting; abnormal bleeding; chest pain; severe headaches; slurred speech; or weakness on one side of the body.** Inform your ophthalmologist as soon as possible of any of these problems.

**Risks (problems this medication may cause)**

**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 follow-up visits or phone calls, you will be checked for possible side effects and the results will be discussed with you.

Any medication has the potential to cause allergic reactions in a small number of people. Symptoms of an allergic reaction can include a rash, hives, itching, shortness of breath, and rarely, death. In general, allergic reactions to medicines are more likely to occur in people who have allergies to other drugs, foods, or things in the environment, such as dust or grass. If you have allergies to other medicines, foods, or other things in the environment, or if you have asthma, you should let your physician know.

**Possible complications and side effects of Xipere®, or the pre-injection preparation procedure, include, but are not limited to:**

* Eye redness
* Eye pain
* Vision loss
* Cataract (clouding of the lens of the eye)
* Glaucoma (increased pressure in the eye)
* Hypotony (reduced pressure in the eye)
* Vitreous floaters
* Vitreous hemorrhage
* Inflammation or damage to the cornea or other parts of the eye
* Eye infection (endophthalmitis). You may receive eye drops with instructions on when to use them to reduce the possibility of this occurring.

Any of these rare complications may lead to severe, permanent loss of vision.

**Possible risk to a fetus (unborn child).** Medications taken during pregnancy can harm the fetus. There are no well-controlled studies with Xipere® in pregnant women to inform drug-associated risk. In animal reproductive studies using mice and rabbits, topical corticosteroids have shown to produce deformity in the unborn fetus including but not limited to cleft palate, embryofetal death, herniated abdominal viscera, hypoplastic kidneys, and craniofacial malformation. There is little systemic exposure following suprachoroidal injection of Xipere®. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Possible risk for breastfeeding.** Many medications are transferred in human milk with the potential for absorption and adverse reactions in the breastfed child. It is not known whether ocular administration of corticosteroids could be transferred in human milk. Systemically administered corticosteroids appear in milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other effects. Women who are breastfeeding should consider the developmental and health benefits of breastfeeding along with the woman’s medical need for Xipere® and potential adverse effects on the breastfed child.

**Alternatives (choices and options)**

Xipere® is not the only option. Your other treatment choices may include:

* No treatment. If you decide not to have treatment, your eye problems can quickly get worse. You could have more vision loss or even blindness.
* Similar steroid medications administered by a different method. These would include eye drops, oral pills, sub-tenon injection, or intravitreal injection.
* Other medications approved by the FDA for treating your type of eye problem.
* Other medications approved by the FDA for a different condition. Ophthalmologists use these medications “off-label” because they may be similar or even have a better effect compared to an FDA-approved medication.
* Your ophthalmologist will let you know if other medications, or a similar medication with a different method of delivery, 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.
* Your ophthalmologist will tell you how these medications could help and the risks (problems) they might cause.

**Consent to Treatment**

**By signing below, you agree and consent to the following:**

* Your ophthalmologist has discussed the information in this consent form with you, and has answered your questions about using Xipere® to treat your eye problem.
* The ophthalmologist explained that you have inflammation and swelling in the back of your eye.
* You consent to keep having Xipere® injections unless you tell your ophthalmologist that you no longer want the medication, or your eye problems or other relevant health issues change so much that there are new risks and benefits to discuss.
* You understand that it is impossible for the ophthalmologist to inform you of every possible complication that may occur.
* If any unforeseen condition arises in the course of the above procedure that, in the ophthalmologist’s judgment, calls for procedures in addition to or different from those now contemplated, you further request and authorize the ophthalmologist or their designees to do whatever they deem advisable.
* Your ophthalmologist has informed you that Betadine® is a proven effective method for surface cleaning of the eye and surrounding areas which reduce the risk of infection. You understand and acknowledge that if you choose to refuse the use of Betadine®, it may increase the risk of infection with this procedure.
* You understand the signs and symptoms to watch for after the injection and agree to report them to your ophthalmologist immediately.
* You understand and accept the risks and benefits of, and alternatives to, receiving this suprachoroidal injection of Xipere®.

I authorize my ophthalmologist to proceed with an injection of Xipere® (triamcinolone acetonide injectable suspension) in my: **\_\_Left** eye \_\_**Right** eye \_\_**Both** eyes at regular intervals, as needed.

Patient’s Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date of Birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Patient Signature (or person authorized to sign for patient) Date

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Printed Name