

# Blurhex<sup>®</sup>

## Trypan Blue Solution Sterile solution for intraocular use only

### COMPOSITION:

Trypan Blue .....	0.06% w/v
Buffered Aqueous Vehicle .....	q. s.

### Clinical pharmacology:

Blurhex selectively stains connective tissue structures in the human eye such as the anterior lens capsule of the human crystalline lens.

### Mechanism of action:

Blurhex selectively stains membranes in the human eye during posterior surgery, such as epiretinal membranes (ERM) and Internal Limiting Membranes (ILM).

### Indication:

Blurhex is indicated for use as an aid in ophthalmic surgery by staining the epiretinal membranes during ophthalmic surgical vitrectomy procedures, facilitating removal of the tissue.

### Dosage and Administration:

Blurhex is intended to be applied directly on the anterior lens capsule, staining any portion of the capsule which comes in contact with the dye. Excess dye is washed out of the anterior chamber. The dye does not penetrate the capsule, permitting visualization of the anterior capsule in contrast to the non-stained lens cortex and inner lens material.

### Contraindications:

Blurhex is contraindicated when a non-hydrated (dry state), hydrophilic Acrylic intraocular lens (IOL) is planned to be inserted into the eye. The dye may be absorbed by the IOL and stain it.

### Warnings and Precautions:

Not for injection

### Excessive staining:

It is recommended that after application all excess Blurhex is immediately removed from the eye by thorough irrigation of the anterior chamber.

Carcinogenesis, mutagenesis, impairment of fertility

Blurhex is carcinogenic in rats. Wister/Lewis rats developed lymphomas after receiving subcutaneous injections of 1% Blurhex dosed at 50 mg/kg every other week for 52 weeks (total dose approximately 1,250,000-fold the maximum recommended human dose of 0.06 mg per injection in a 60 kg person, assuming total absorption).

Blurhex was mutagenic in the Ames test and caused DNA strand breaks in vitro.

Use in specific populations section

### Pregnancy

### Teratogenic Effects

### Pregnancy Category C.

Blurhex is teratogenic in rats, mice, rabbits, hamsters, dogs, guinea pigs, pigs, and chickens. The majority of teratogenicity studies performed involve intravenous, intraperitoneal, or subcutaneous administration in the rat. The teratogenic dose is 50 mg/kg as a single dose or 25 mg/kg/day during embryogenesis in the rat. These doses are approximately 50,000- and 25,000-fold the maximum recommended human dose of 0.06 mg per injection based in a 60 kg person, assuming that the whole dose is completely absorbed.

Characteristic anomalies included neural tube, cardiovascular, vertebral, tail, and eye defects. Blurhex also caused an increase in post-implantation mortality, and decreased fetal weight. In the monkey, Blurhex caused abortions with single or two daily doses of 50 mg/kg between 20th to 25th days of pregnancy, but no apparent increase in birth defects (approximately 50,000-fold maximum recommended human dose of 0.06 mg per injection, assuming total absorption). There are no adequate and well-controlled studies in pregnant women. Blurhex should be given to a pregnant woman only if the potential benefit justifies the potential risk to the fetus.

### **Nursing mothers**

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Blurhex is administered to a nursing woman.

### **Pediatric use**

The safety and effectiveness of Blurhex have been established in pediatric patients.

Use of Blurhex is supported by evidence from an adequate and well-controlled study

### **Side effect:**

Adverse reactions reported following use of Blurhex include discoloration of high water content hydrogen intraocular lenses (see contraindications) and inadvertent Staining of the posterior lens capsule and vitreous face. Staining of the posterior lens Capsule or staining of the vitreous face is generally self-limited, lasting up to one week.

**Overdose:** No information provided.

### **Storage:**

Store in a cool & dark place. Protect from light

**Presentation:** 10 vials of 1 ml packed in a carton along with QR code for Product Information

Keep the medicines out of reach of children.

Prescription only medicine

Manufactured by:

**Divine Laboratories Pvt. Ltd.**

Block No. 471, Dabhasa, Tal-Padra,

Dist- Vadodara - 391 440, India.

Marketed by:

**Senses Pharmaceuticals Pvt. Ltd.,**

#124, 5th Cross Rd, K. N. Extension, Stage 2, Yeshwanthpur Industrial Suburb,  
Yeshwanthpur, Bengaluru, - 560 022, Karnataka, India.

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