

## HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use IHEEZO™ safely and effectively. See full prescribing information for IHEEZO™.

**IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3%, for topical ophthalmic use**

Initial U.S. Approval: 1955

### INDICATIONS AND USAGE

IHEEZO™ is an ester anesthetic indicated for ocular surface anesthesia. (1)

### DOSAGE AND ADMINISTRATION

- The recommended dose of IHEEZO™ is 3 drops applied topically to the ocular surface in the area of the planned procedure. (2)
- IHEEZO™ may be reapplied as needed to maintain anesthetic effect. (2)

### DOSAGE FORMS AND STRENGTHS

IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3% contains 24 mg of chloroprocaine hydrochloride per vial (800 mg). Clear, colorless to light yellow gel in single patient use vial. (3)

### CONTRAINDICATIONS

IHEEZO™ is contraindicated in patients with a history of hypersensitivity to any component of this preparation. (4)

### WARNINGS AND PRECAUTIONS

- Not for Injection or Intraocular Administration (5.1).
- Corneal Injury Due to Insensitivity (5.2).
- Corneal Opacification (5.3)
- For Administration by Healthcare Provider: IHEEZO™ is not intended for patient self-administration (5.5).

### ADVERSE REACTIONS

Most common adverse reaction is mydriasis (approximately 25%) (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Harrow at 1-833-4HARROW(427769) or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

See 17 for PATIENT COUNSELING INFORMATION

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\*Sections or subsections omitted from the full prescribing information are not listed.

## FULL PRESCRIBING INFORMATION

### 1 INDICATIONS AND USAGE

IHEEZO™ is indicated for ocular surface anesthesia.

### 2 DOSAGE AND ADMINISTRATION

The recommended dose of IHEEZO™ is 3 drops applied topically to the ocular surface in the area of the planned procedure. IHEEZO™ may be reapplied as needed to maintain anesthetic effect.

### 3 DOSAGE FORMS AND STRENGTHS

IHEEZO™ (chloroprocaine hydrochloride ophthalmic gel) 3% contains 24 mg of chloroprocaine hydrochloride per vial (800 mg of gel).

### 4 CONTRAINDICATIONS

IHEEZO™ is contraindicated in patients with a history of hypersensitivity to any component of this preparation.

### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Not for Injection or Intraocular Administration

IHEEZO™ should not be injected or intraocularly administered.

#### 5.2 Corneal Injury Due to Insensitivity

Patients should not touch the eye for at least 10 to 20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye.

#### 5.3 Corneal Opacification

Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification and ulceration with accompanying visual loss.

#### 5.4 Risk of Contamination

Do not touch the dropper tip to any surface as this may contaminate the gel.

#### 5.5 For Administration by Healthcare Provider

IHEEZO™ is indicated for administration under the direct supervision of a healthcare provider. IHEEZO™ is not intended for patient self-administration.

### 6 ADVERSE REACTIONS

#### 6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction

rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The data described below reflect 201 patients undergoing various surgical ocular procedures in two placebo-controlled trials (Study 1 and Study 2). Patients in Study 1 were randomized to receive a single instillation of 3 drops of IHEEZO™ or placebo. Patients in Study 2 were randomized to receive a single or multiple instillations of 1, 3 or 3+3 drops of IHEEZO™ or placebo.

The most common adverse reactions in these studies, (incidence greater than or equal to 5%) following IHEEZO™ administration were mydriasis, conjunctival hyperemia and eye irritation.

#### Adverse Reactions Reported in Controlled Trials

**Table 1. Adverse Reactions in 5% or more of IHEEZO™ Treated Patients in Studies 1 and 2**

	IHEEZO™	Placebo
<b>Preferred Term</b>	<b>N=151 n (%)</b>	<b>N=50 n (%)</b>
Mydriasis	39 (26%)	1 (2%)
Conjunctival hyperemia	16 (11%)	6 (12%)
Eye irritation	9 (6%)	2 (4%)

### 8 USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

##### Risk Summary

There are no adequate and well-controlled studies of IHEEZO™ use in pregnant women to inform a drug associated risk. There are no animal reproduction studies for chloroprocaine.

#### 8.2 Lactation

##### Risk Summary

There are no data on the presence of chloroprocaine in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for IHEEZO™ and any potential adverse effects on the breastfed infant from IHEEZO™.

