

# Dextenza<sup>®</sup>

(dexamethasone ophthalmic insert) 0.4 mg  
for intracanalicular use

**BRIEF SUMMARY:** Please see the DEXTENZA Package Insert for full prescribing information for DEXTENZA (06/2019)

## 1 INDICATIONS AND USAGE

DEXTENZA<sup>®</sup> (dexamethasone ophthalmic insert) is a corticosteroid indicated for the treatment of ocular inflammation and pain following ophthalmic surgery.

## 4 CONTRAINDICATIONS

DEXTENZA is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.

## 5 WARNINGS AND PRECAUTIONS

### 5.1 Intraocular Pressure Increase

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be monitored during the course of the treatment.

### 5.2 Bacterial Infection

Corticosteroids may suppress the host response and thus increase the hazard for secondary ocular infections. In acute purulent conditions, steroids may mask infection and enhance existing infection [see Contraindications (4)].

### 5.3 Viral Infections

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex) [see Contraindications (4)].

### 5.4 Fungal Infections

Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate [see Contraindications (4)].

### 5.5 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

## 6 ADVERSE REACTIONS

The following serious adverse reactions are described elsewhere in the labeling:

- Intraocular Pressure Increase [see Warnings and Precautions (5.1)]
- Bacterial Infection [see Warnings and Precautions (5.2)]
- Viral Infection [see Warnings and Precautions (5.3)]
- Fungal Infection [see Warnings and Precautions (5.4)]
- Delayed Healing [see Warnings and Precautions (5.5)]

### 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. Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation; delayed wound healing; secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera [see Warnings and Precautions (5)].

DEXTENZA was studied in four randomized, vehicle-controlled studies (n = 567). The mean age of the population was 68 years (range 35 to 87 years); 59% were female, and 83% were white. Forty-seven percent had brown iris color and 30% had blue iris color. The most common ocular adverse reactions that occurred in patients treated with DEXTENZA were: anterior chamber inflammation including iritis and iridocyclitis (10%); intraocular pressure increased (6%); visual acuity reduced (2%); cystoid macular edema (1%); corneal edema (1%); eye pain (1%) and conjunctival hyperemia (1%).

The most common non-ocular adverse reaction that occurred in patients treated with DEXTENZA was headache (1%).

## 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

#### Risk Summary

There are no adequate or well-controlled studies with DEXTENZA in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. In animal reproduction studies, administration of topical ocular dexamethasone to pregnant mice and rabbits during organogenesis produced embryofetal lethality, cleft palate and multiple visceral malformations [see Animal Data].

#### Data

##### Animal Data

Topical ocular administration of 0.15% dexamethasone (0.75 mg/kg/day) on gestational days 10 to 13 produced embryofetal lethality and a high incidence of cleft palate in a mouse study. A daily dose of 0.75 mg/kg/day in the mouse is approximately 5 times the entire dose of dexamethasone in the DEXTENZA product, on a mg/m<sup>2</sup> basis. In a rabbit study, topical ocular administration of 0.1% dexamethasone throughout organogenesis (0.36 mg /day, on gestational day 6 followed by 0.24 mg/day on gestational days 7-18) produced intestinal anomalies, intestinal aplasia, gastroschisis and hypoplastic kidneys. A daily dose of 0.24 mg/day is approximately 6 times the entire dose of dexamethasone in the DEXTENZA product, on a mg/m<sup>2</sup> basis.

### 8.2 Lactation

Systemically administered corticosteroids appear in human milk and could suppress growth and interfere with endogenous corticosteroid production; however the systemic concentration of dexamethasone following administration of DEXTENZA is low [see Clinical Pharmacology (12.3)]. There is no information regarding the presence of DEXTENZA in human milk, the effects of the drug on the breastfed infant or the effects of the drug on milk production to inform risk of DEXTENZA to an infant during lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for DEXTENZA and any potential adverse effects on the breastfed child from DEXTENZA.

### 8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

### 8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

## 17 PATIENT COUNSELING INFORMATION

Advise patients to consult their surgeon if pain, redness, or itching develops.

**Ocular**  
Therapeutix™

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# Lowell A. Gess, MD, Chang Humanitarian

## \$50,000 grant will benefit the Lowell and Ruth Gess Eye Hospital

**W**hen you ask Lowell A. Gess, MD, for interesting stories from his career, make sure to be seated in a comfortable chair. The anecdotes roll by so quickly it can be hard to catch them all. Dr. Gess once paused performing cataract surgery to deliver a baby, was one of the earliest adopters of the IOL, his medical education and training took more than 25 years to complete because he couldn't stop charitable work in Sierra Leone and Nigeria, and one of his earliest surgeries involved saving the life of a man who was injured by a spear in a wedding feast gone awry.

Dr. Gess's career spans so many years and covers such a wide breadth of the world it can feel less like the story of one man's life and more like the story of modern ophthalmology itself. It's the whole of his story, the whole of his life dedicated to charitable eyecare, that makes the ASCRS Foundation so proud to name him the 2020 Chang



Lowell A. Gess, MD  
Source: Gess family



# selected for 2020 ASCRS Foundation Award

Humanitarian awardee. Endowed by a generous gift from David and Victoria Chang, the ASCRS Foundation Chang Humanitarian Award was established to honor and recognize outstanding humanitarian work with a focus on cataract blindness and disability. The award will be given to him at the 2020 ASCRS Annual Meeting in Boston, Massachusetts.

Dr. Gess's philosophy toward charity can be described in his own words: "I face a humanity too precious to neglect. ... I am experiencing an adventure too thrilling to miss." With more than 50 years of work in charitable care, 18 of which were as a commissioned medical missionary and 32 as a volunteer eye surgeon, his thrilling adventure has spanned generations. His travel back and forth from the United States to Nigeria, Zimbabwe, and Sierra Leone, where his namesake hospital stands today, combines to almost 200 trips across the Atlantic.

He discovered his true passion when, as a general surgeon in 1952, he encountered countless people who were blind and in desperate need of eyecare but with no ophthalmologists available.

Over the next several years, Dr. Gess rotated between ophthalmic education and residency in the United States and charitable missions to Sierra Leone. Soon, he and his family moved there full time so they could continue serving this community so desperately in need. There seemed to be no roadblock that could slow Dr. Gess's deep dedication to helping better the world. Even literal roadblocks were no obstacle; Dr. Gess traveled with ease through roadblocks during the Sierra Leone Civil War because he had helped so many people that he was well known. Eventually he and his wife, with support from the United Methodist Church, founded the Lowell and Ruth Gess (Kissy UMC) Eye Hospital to serve the eye needs in Sierra Leone. When the Ebola epidemic struck, Dr. Gess volunteered to help and was the only fully trained ophthalmologist present to attend to the post-Ebola survivors.

John Berdahl, MD, who nominated Dr. Gess explained, "At age 94, he bought tickets to Africa without the knowledge of his family

to help those stricken by Ebola. His rationale was: "Who better than me?" Since his arrival in West Africa in 1952, Dr. Gess has participated in more than 20,000 eye and general surgery procedures, changing countless lives.

Dr. Gess's quiet and gentle spirit along with the persistence of his commitment have made him beloved in Sierra Leone. His determination to see past cultural difference has allowed him to connect with and train hundreds of local medical practitioners. His ophthalmologist son, Timothy Gess, MD, said, "Dr. Lowell Gess's passion and compassion has led him through all these years of service, and real sacrifice has been made to help people in Africa. Civil war and the Ebola crisis could not keep my father away." He has seen ophthalmology through from its earliest stages to its modern iterations. There is no other career quite like Dr. Gess's, and his determination to give the whole of his life to charitable care is unparalleled.

Dr. Chang said that the nominating committee was awestruck by Dr. Gess's career as a volunteer ophthalmologist in West Africa for more than 60 years. "He was an early adopter of IOLs and one of the earliest members of ASCRS," Dr. Chang said. "But he would annually take 3 months off from his Minnesota private practice to volunteer in Sierra Leone, where he established and supported the country's main eye hospital," he said. "His most recent trip to Sierra Leone to help Ebola survivors was this past summer—at the age of 98."

"It was good fortune to get into eyecare," Dr. Gess said. "With renewed sight, the patient walks without being led, resumes a productive life that provides for food, shelter, and family needs and assumes a new dignity. You can understand that their first words following cataract extraction with intraocular lens implantation often are "Thank God!" Dr. Gess's lifelong work is extraordinary and truly inspirational, and the ASCRS Foundation is incredibly pleased to honor him with this year's Chang Humanitarian Award. Dr. Gess has earmarked the \$50,000 grant to the Lowell and Ruth Gess Eye Hospital to help expand facilities and provide a more complete eyecare program in Sierra Leone. 🍷

by Julia Donaldson  
ASCRS Foundation Coordinator

## About the award

For more than 18 years, the ASCRS Foundation has fostered programs to alleviate the worldwide backlog of cataract. The ASCRS Foundation's work is only possible because of the many individuals and partner organizations who volunteer their time, expertise, and financial support to treat cataract blindness around the world. "David and Victoria's generosity and leadership is deeply appreciated because it allows us to highlight and perpetuate the noble volunteer efforts of our colleagues within ophthalmology who are trying to alleviate treatable global blindness," said Stephen Lane, MD, past co-chair of the ASCRS Foundation.

## Contact

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