

## **PATIENT IMPORTANT SAFETY INFORMATION**

This summary contains risk and safety information for patients about DEXTENZA (dexamethasone), a prescription corticosteroid (or steroid). It does not include all the information about DEXTENZA and does not take the place of talking to your healthcare provider about your medical condition or treatment.

### **What is DEXTENZA?**

**DEXTENZA, a corticosteroid (or steroid) medicine, is used:**

- To treat ocular (eye) inflammation (redness, swelling) and pain of the eye following eye surgery
- To treat eye itching associated with allergic conjunctivitis

### **What is the most important information I should know about DEXTENZA?**

**DEXTENZA can cause serious side effects, including:**

- **Increase Pressure in the Eye:** Use of steroids for long periods may cause high pressure in the eye. This high pressure may lead to glaucoma, which can harm your vision. Your physician should check your eye pressure during therapy with DEXTENZA.
- **Eye Infections:** Use of steroids can mask the signs of an eye infection and may prolong the infection or make it worse. Tell your doctor if you develop an eye infection while DEXTENZA is present.
- Use of steroids after eye surgery may slow down healing or cause blister formation on the eye.
- DEXTENZA is prescribed by a physician after an appropriate eye examination is performed. If signs and symptoms fail to improve after 2 days, you should be re-evaluated

### **Who should not use DEXTENZA?**

Patients who have active eye infections should not use DEXTENZA.

### **Before taking DEXTENZA, what should I tell my healthcare provider?**

Tell your healthcare provider about all of your medical conditions, including if you:

- Have a history of glaucoma or high eye pressure
- Have an active eye infection or a history of eye infections
- Are pregnant or planning to become pregnant or if you are breastfeeding or planning to breastfeed. The use or effects of DEXTENZA in pregnant women or in infants of breastfeeding women has not been evaluated.

### **What are the side effects of DEXTENZA?**

See “**What is the most important information I should know about DEXTENZA?**”.

**The most common side effects of DEXTENZA for treatment of inflammation and pain following eye surgery were:**

- Swelling of the front of the eye, including the iris—the colored area surrounding the pupil—and in the iris-associated muscle (anterior chamber inflammation, including iritis and iridocyclitis)
- Increased pressure in the eye (intraocular pressure increased)
- Problems with seeing clearly (visual acuity reduced)
- Cyst-like swelling in the back of the eye (cystoid macular edema)
- Swelling of the clear front surface of the eye (corneal edema)
- Eye pain
- Redness of the eye (conjunctival hyperemia)
- Headache

**The most common side effects of DEXTENZA for treatment of eye itching associated with allergic conjunctivitis were:**

- Increased pressure in the eye (intraocular pressure increased)
- Increased tearing of the eye (lacrimation increased)
- Eye discharge
- Problems with seeing clearly (visual acuity reduced)
- Headache

These are not all the possible side effects of DEXTENZA. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider about any side effect that bothers you or that does not go away. **Call your doctor for medical advice about side effects.** You may report side effects to FDA at 1-800-FDA-1088. You may also contact Ocular Therapeutix at 1-800-339-8369.

Please [click here](#) for full Prescribing Information.