DEXYCU is a corticosteroid indicated for the treatment of postoperative inflammation.

### Dosage and Administration

**Dosage Form and Strengths**

Intraocular suspension: 9% equivalent to dexamethasone 103.4 mg/mL in a single-dose vial.

**Initial U.S. Approval:** 1958

**Dosing Information**

- Administer 0.005 mL of DEXYCU into the posterior chamber inferiorly behind the iris at the end of ocular surgery.

**Preparation and Administration**

The DEXYCU administration kit contains the following items:

- One glass vial: 0.5 mL of DEXYCU
- One sterile 1-mL syringe
- One sterile syringe guide
- One sterile syringe ring
- One sterile 18-gauge needle (1 1/2 inches long), plastic cap attached
- One sterile 25-gauge bent cannula (8 mm long), plastic cap attached

**Preparation**

1. Prepare a sterile field.
   - Remove the components of the administration kit from their respective pouches:
     - syringe
     - syringe guide
     - syringe ring
     - needle
     - cannula
   - Place onto the sterile field.

2. Withdraw the syringe plunger approximately 1 inch.
   - Place the syringe ring on the plunger (slit facing the plunger).
   - Apply slight downward pressure until the syringe ring “snaps” into place.

3. Place the 18-gauge needle firmly on the syringe.
   - Remove the cap from the needle.
   - Depress the plunger completely and then withdraw the plunger to fill the syringe with air.

4. Invert the vial.
   - Remove the blue plastic flip-cap from the vial and wipe the top of rubber stopper with an alcohol pad.
   - Lightly tap/flick the barrel of the syringe to remove any excess drug from the tip, and remove the plastic cap.
   - Affix the syringe guide over the syringe ring on the plunger.

5. Mix using a vortex mixer or vigorously shake the vial of DEXYCU sideways for a minimum of 30 seconds.
   - The suspended drug material must be used immediately after shaking.

6. One sterile 25-gauge bent cannula (8 mm long), plastic cap attached

**Intravitreal Administration**

- Administer 0.005 mL of DEXYCU into the posterior chamber inferiorly behind the iris at the end of ocular surgery.

**Contraindications**

None (4).

**Warnings and Precautions**

- Increase in Intraocular Pressure (IOP): Monitor for increases in IOP (5.1).
- Delayed Healing: Monitor for delayed healing (5.2).
- Infection Exacerbation: Monitor and treat for any exacerbations of bacterial, viral or fungal infections (5.3).
- Cataract Progression: Cataracts may develop or progress in phakic patients (5.4).

**Adverse Reactions**

In controlled studies, the most common adverse reactions reported by 5-15% of patients were intraocular pressure increased, corneal edema and iritis.

**How Supplied/Storage and Handling**

Each kit of DEXYCU is for a single administration. After preparation, 0.005 mL will be administered.

**Clinical Studies**

STEM: Monitor and treat for any exacerbations of bacterial, viral or fungal infections.

**Revised:** 6/2020
8.4 Pediatric Use
Safety and effectiveness of DEXYCU in pediatric patients have not been established.

8.5 Geriatric Use
No overall differences in safety or effectiveness have been observed between older and younger patients.

11 DESCRIPTION
DEXYCU (dexamethasone intraocular suspension) 9% is a corticosteroid, sterile, white to off-white opaque suspension for intraocular administration. Each mL of DEXYCU contains 0.5 mL of 9%/w/v dexamethasone suspension equivalent for 0.517 mg of dexamethasone. The inactive ingredient is asparaginyl citrate. DEXYCU does not contain an antimicrobial preservative.

The chemical name of dexamethasone is pregn-11,21-diene-2,16-dione-16,17β-diol-17α-hydroxy-11β-fluoro-11α,16α,21-trihydroxy-16-methyl-, (11β,16α). It has a molecular formula of C₃₄H₄₃FO₂ and a molecular weight of 592.64 g/mole. Its structural formula is:

[Chemical structure diagram]

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Dexamethasone is a corticosteroid. Corticosteroids have been shown to suppress inflammation by inhibiting multiple inflammatory cytokines resulting in decreased edema, fibrin deposition, capillary leakage and migration of inflammatory cells.

12.3 Pharmacokinetics
Systemic exposure to dexamethasone was evaluated in a subgroup of patients enrolled in two studies (n=25 for the first study and n=13 for the second study). The patients received a single intraocular injection of DEXYCU containing 342 µg or 517 µg of dexamethasone at the end of cataract surgery and blood samples were selected prior to surgery and at one or more time points post-surgery between Day 1 and up to Day 30. In the first study, the dexamethasone plasma concentrations on post-surgery Day 1 ranged from 0.09 to 0.61 ng/mL and from 0.07 to 1.16 ng/mL, following administration of DEXYCU 342 µg and 517 µg, respectively. In the second study, dexamethasone plasma concentrations on post-surgery Day 1 ranged from 0.349 to 2.79 ng/mL, following administration of DEXYCU 517 µg. In both the studies, dexamethasone plasma concentrations declined over time and very few patients had quantifiable dexamethasone plasma concentrations at the final time point of sampling (Day 15 or Day 30).

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Animal studies have not been conducted to determine whether DEXYCU has the potential for carcinogenesis or mutagenesis. Fertility studies have not been conducted in animals.

14 CLINICAL STUDIES
Clinical efficacy was evaluated in a randomized, double-masked, placebo-controlled trial (NCT0200688H) in which subjects received either DEXYCU or placebo (vehicle). A dose of 5 micrograms of DEXYCU (equivalent to 507 micrograms of dexamethasone), a dose equivalent to 342 micrograms of dexamethasone or vehicle, was administered by the physician at the end of the surgical procedure. The primary efficacy endpoint for the study was the proportion of patients with anterior chamber cell clearing (i.e., cell score=0) on postoperative day 30 (P00). The percentage of anterior cells was assessed using a slit lamp biomicroscope up to 30 days post treatment. The percentage of patients with anterior chamber clearing at Day 30 was 20% in the placebo group, and 57% and 60% in the 342 and 507 microgram treatment groups, respectively (Table 1). The percentage of subjects receiving rescue medication of ocular steroid or RAIO was significantly lower on Day 8, 15 and 30 in the 342 and 517 microgram treatment groups compared to placebo (Table 2).

Table 1: Proportion of subjects with clearing of the anterior chamber cells by visit

<table>
<thead>
<tr>
<th>Visits</th>
<th>Treatments</th>
<th>Placebo N=80</th>
<th>DEX342 N=156</th>
<th>DEX517 N=156</th>
<th>DEX342 vs Placebo</th>
<th>DEX517 vs Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 8</td>
<td>70(88%)</td>
<td>37(24%)</td>
<td>43(28%)</td>
<td>60(38%)</td>
<td>16(24%)</td>
<td>21(14%)</td>
</tr>
<tr>
<td>Day 15</td>
<td>13(16%)</td>
<td>60(48%)</td>
<td>44(28%)</td>
<td>22(14%)</td>
<td>9(13%)</td>
<td>16(10%)</td>
</tr>
<tr>
<td>Day 30</td>
<td>16(20%)</td>
<td>90(62%)</td>
<td>59(38%)</td>
<td>40(27%)</td>
<td>40(27%)</td>
<td>40(27%)</td>
</tr>
<tr>
<td>Day 45</td>
<td>12(15%)</td>
<td>83(58%)</td>
<td>60(38%)</td>
<td>36%</td>
<td>36%</td>
<td>36%</td>
</tr>
<tr>
<td>Day 60</td>
<td>13(16%)</td>
<td>112(76%)</td>
<td>70(45%)</td>
<td>66%</td>
<td>66%</td>
<td>66%</td>
</tr>
</tbody>
</table>

Subjects who received rescue medication were included in analysis.

Table 2: Proportion of subjects requiring rescue medications

<table>
<thead>
<tr>
<th>Visits</th>
<th>Number (Percent) of Patients Receiving Rescue Medication, and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo N=80</td>
<td>DEX342 N=156</td>
</tr>
<tr>
<td>Day 8</td>
<td>16(20%)</td>
</tr>
<tr>
<td>Day 15</td>
<td>16(20%)</td>
</tr>
<tr>
<td>Day 30</td>
<td>16(20%)</td>
</tr>
</tbody>
</table>

Subjects who received an ocular corticosteroid or RAIO in study visit.

16 HOW SUPPLIED/STORAGE AND HANDLING
Each kit of DEXYCU contains a single dose for a single patient. The 2 mL glass vial is filled with 0.5 mL of 9%/w/v dexamethasone intraocular suspension and has a blue cap (NDC 71879-001-01). Each kit also contains one sterile 16-gauge, 1-1/2 inch needle with a plastic cap attached, one sterile plastic-1 mL syringe with a glass cap attached to the intraocular administration, and one sterile assembly pouch containing a sterile ring and a sterile syringe guide used for measuring and injection of the 0.5 mL dose. Store at 20°C to 25°C (68°F to 77°F).

Manufactured for: Eyepoint Pharmaceuticals US Inc., Watertown, MA 02472