About DEXYCU®

The first and only FDA-approved, single-dose, sustained-release, intracameral steroid for the treatment of postoperative inflammation¹⁻³

PRODUCT INFORMATION¹

Product Name: DEXYCU
Delivery: intraocular suspension
Active Ingredient: dexamethasone 9%
Inactive Ingredient: acetyl triethyl citrate (no antimicrobial preservative)
Description: DEXYCU® (dexamethasone intraocular suspension) 9% is a corticosteroid, sterile, white to off-white opaque suspension for intraocular administration. Each vial of DEXYCU contains 0.5 mL of 9% w/w dexamethasone suspension equivalent to 51.7 mg of dexamethasone.
How Supplied: 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% dexamethasone intraocular suspension and has a blue cap.

INDICATION AND USAGE¹

DEXYCU® (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

Please see Important Safety Information throughout and accompanying full Prescribing Information.

PACKAGING SPECIFICATIONS¹

1. One glass vial of 0.5 mL of DEXYCU
2. One sterile 1-mL syringe
3. One sterile syringe guide
4. One sterile syringe ring
5. One sterile 18-gauge needle (1½ inches long), plastic cap attached
6. One sterile 25-gauge bent cannula (8 mm long), plastic cap attached

NDC Number: 71879-0001-01
Storage Conditions: 20°C to 25°C (68°F to 77°F)
DEXYCU has a 2-year shelf life.³
How does DEXYCU work?

Delivers sustained release of dexamethasone at the site using patented Verisome® Technology

DEXYCU utilizes a novel, biodegradable, sustained-release platform, Verisome Technology, to deliver the active ingredient, dexamethasone.4

- The sphere formation is in aqueous media, which keeps the delivery system intact4
- Provides a controlled release of dexamethasone across the target area3
- Allows for direct and immediate treatment that will self-taper over time until the sphere is no longer visible2,4

When is DEXYCU administered?

DEXYCU helps put control in place with a single self-tapering dose.1,2

- In a single slow motion, inject 0.005 mL of the drug material behind the iris in the inferior portion of the posterior chamber1

- If the sphere of administered drug after intraocular injection appears to be larger than 2 mm in diameter, excess drug material may be removed by irrigation and aspiration in the sterile surgical setting1

- PLEASE NOTE: Some drug material will remain in the syringe after the injection—this is necessary for accurate dosing. Discard unused portion remaining in the syringe after administration1

- DEXYCU may be visible in the eye during a follow-up visit until its complete dissolution4

While DEXYCU does not replace all drops, this one-time treatment may replace over 70 steroid drops.1,5

The cumulative percentage of subjects receiving rescue medication of ocular steroid or nonsteroidal anti-inflammatory drug (NSAID) by day 30 was significantly lower in the DEXYCU (517 mcg) treatment group (20%; n=31/156) compared to placebo (54%; n=43/80).1

INDICATION AND USAGE

DEXYCU® (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

IMPORTANT SAFETY INFORMATION

CONTRAINdications

None.

Please see Important Safety Information throughout and accompanying full Prescribing Information.
Reimbursement

PASS-THROUGH STATUS

Allows ASCs and HOPDs to bill Medicare and other payers for DEXYCU® (dexamethasone intraocular suspension) 9% using a unique J-code—J1095. The payment is over and above the facility fees paid to ASCs or to HOPDs for cataract surgery.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Short Description</th>
<th>Long Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1095</td>
<td>Injection, dexamethasone 9%</td>
<td>Injection, dexamethasone 9 percent, intraocular, 1 microgram</td>
</tr>
</tbody>
</table>

CMS (Medicare) billing methodology for many specialty products is to the single unit of measure. For DEXYCU, 1 unit=1 microgram. Allowable billing for DEXYCU is 517 units.

No effect on physician fees
Payment to the surgeon for cataract surgery under Medicare’s Physician Fee Schedule will be unaffected by the use of DEXYCU or the pass-through payments related to DEXYCU, now and in the future.

No effect on the healthcare system
The pass-through regulation is budget-neutral to the healthcare system. To the extent that ophthalmic surgeons/facilities elect not to access pass-through payments, the funds set aside will be used by other specialties. Any remaining amounts will be lost to the system.

MEDICARE PART B

- Pass-through products are paid separately (ie, in addition to the packaged procedural payment) by CMS
- DEXYCU use in ocular surgeries (ie, cataract or lens replacement surgery) for patients with Medicare Part B coverage is separately reimbursed
- Pass-through status allows reimbursement for DEXYCU separate from the packaged APC reimbursement for the surgical procedure
- For pass-through drugs, CMS sets the payment rate at the ASP + 6%
  - Check the CMS website for current quarterly reimbursement rates in the Hospital OPPS or ASC Payments sections
- Payment rates are updated quarterly by CMS and will be reduced during a government sequester to 4.3%
- No copay in HOPDs
- 20% copay in ASCs
  - Approximately 90% of Medicare Part B patients have some form of supplemental insurance, which covers copays

IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS

Increase in Intraocular Pressure
- Prolonged use of corticosteroids, including DEXYCU, 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

Please see Important Safety Information throughout and accompanying full Prescribing Information.
**MEDICARE PART C (MEDICARE ADVANTAGE)**

- Medicare Advantage plans will cover DEXYCU, similar to traditional Medicare Part B, but the reimbursement rate may differ from traditional Part B or be subject to payer-specific facility contractual limitations. EyePoint does not guarantee payment by any payer.
- The specific Medicare Advantage payer should be contacted in advance to determine the level of reimbursement.

**COMMERCIAL BILLING AND REIMBURSEMENT**

Coverage and reimbursement may vary by payer, contractual agreements, and site of service. Work with your DEXYCU representative or field reimbursement manager to determine billable status for your payers and identify which plans allow for separate payment of drugs, new technologies, and pass-through drugs.

**Commercial patient reimbursement**

For patients for whom DEXYCU is covered by commercial insurance, patients pay as little as $25 (Maximum Benefit of $350). See the Assistance Programs tab for more information on EyePoint Assist™. Other restrictions may apply.

**Tips for Medicare Advantage and commercial payers**

- Confirm if facility-specific payer contracts allow for separate payment of drugs, new technologies, and pass-through drugs.
- Double-check and verify payer payment/fee schedules for DEXYCU.
- Confirm acceptance of J-code and payer-specific use of appropriate revenue code.

For more information about reimbursement visit DEXYCU.com

**Merit-based Incentive Payment System (MIPS)**

DEXYCU will not be included in MIPS for 2020. Contact your DEXYCU representative for more information.

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APC= Ambulatory Payment Classification; ASC= Ambulatory Surgery Center; ASP= Average Sales Price; CMS= Centers for Medicare & Medicaid Services; HCPCS= Healthcare Common Procedure Coding System; HOPD= Hospital Outpatient Department; OPPS= Outpatient Prospective Payment System; WAC= Wholesale Acquisition Cost.

*Based on currently available information and subject to change without notice. Individual plan coverage, policies, and procedures may vary and should be confirmed. EyePoint does not guarantee coverage or payment.

†To be eligible for EyePoint Assist, patients must be enrolled prior to surgery. Program is subject to change without notice. For any eligible patient, (1) the facility receives a free DEXYCU kit prior to surgery, and (2) the patient’s insurance carrier(s) should not be billed for DEXYCU.
Assistance programs are available through EyePoint Assist* as resources to patients. A representative can provide more background on how EyePoint Assist can help, and additional information can be found online at DEXYCU.com.†

**Patient Assistance Program**

**Assistance for financially eligible uninsured, government insured, and commercially insured patients**

- Eligible patients may receive DEXYCU® (dexamethasone intraocular suspension) 9% at no cost
- Free kit will be sent to your facility prior to surgery
- Application for free kit must be submitted at least 5 days prior to date of surgery
- Please contact your DEXYCU representative for more details

**Copay Assistance Program**

**Patients may pay as little as $25**

EyePoint Assist provides commercial patient reimbursement. For patients for whom DEXYCU is covered by commercial insurance, patients may pay as little as $25 (Maximum Benefit of $350). Other restrictions may apply.

If you have any questions, please call EyePoint Assist at 1-833-EYEPOINT (1-833-393-7646), option 2, Monday through Friday, 8:30 AM – 8:00 PM ET

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**IMPORTANT SAFETY INFORMATION (cont’d)**

**WARNINGS AND PRECAUTIONS (cont’d)**

**Delayed Healing**

- The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation
- In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of corticosteroids

**Exacerbation of Infection**

- The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures
- Use of a corticosteroid in the treatment of patients with a history of herpes simplex requires caution and may prolong the course and may exacerbate the severity of many viral infections

Please see Important Safety Information throughout and accompanying full Prescribing Information.
The DEXYCU Assurance Program process

EyePoint Pharmaceuticals will provide a discount on future orders for any unit of DEXYCU that is denied reimbursement through commercial or Medicare Advantage coverage when all program requirements are met.‡

- When provider follows all required steps for qualifying patients, provider is eligible to receive a discount

**STEP 1**

**Verify coverage with the payer**

To be eligible for a discount on future orders, provider must follow all requirements identified by the benefits investigation. Only patients covered under commercial or Medicare Advantage are eligible. The program is not valid for patients who are covered under Medicaid or Medicare.

- Conduct benefits investigation
- Results of benefits investigation indicate patient has coverage for DEXYCU
- If required by the payer, provider must obtain Prior Authorization, Pre-Certification, or Pre-Determination
- Administer purchased unit of DEXYCU to patient
- Provider must submit claim per payer billing and coding requirements

**STEP 2**

**Request discount§**

- If the provider denies initial claim, complete the DEXYCU Assurance Program Request Form and fax it with the required documentation to the number on the form¶
- Receive a 16.6% discount off the next 6 orders of DEXYCU

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*To be eligible for EyePoint Assist, patients must be enrolled prior to surgery. Program is subject to change without notice. For any eligible patient, (1) the facility receives a free DEXYCU kit prior to surgery, and (2) the patient’s insurance carrier(s) should not be billed for DEXYCU.

†Coverage and reimbursement vary and should be confirmed by facility. EyePoint does not guarantee reimbursement.

‡Discount of 16.6% off next 6 orders cannot be combined with additional rebate programs.

§Eligibility for the 6-unit discount described herein is limited to 120 days from date of service (i.e., administration date). Claims must be received by June 30, 2020.

¶An authorization number will be issued upon approval; no paperwork will be provided during this step.
Sample CMS-1500 Paper Claim Form

**Enter all applicable patient information**

When using J-code for DEXYCU based on instruction from payer, please include NDC on line '19

**Item 21:** Enter "0" if using ICD-10-CM

**Item 21:** Enter the Diagnosis Code(s)

**Item 24B:** "24" indicates an ASC

**Item 24D:** Enter the applicable procedure code (eg, 66984 for cataract surgery)

**Item 24D:** Enter the unique Billing Code for DEXYCU

**Item 24D:** Enter the Modifier for left eye (LT) or right eye (RT)

**Item 24F:** Enter price for DEXYCU from price schedule, including all applicable markups

**Item 24G:** Enter the number of Units. For DEXYCU, 1 unit= 1 microgram. Allowable billing for DEXYCU is 517 units

**Item 33a:** Entry of NPI Number is required

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Information contained herein is provided as a reference for obtaining appropriate and accurate reimbursement. This content is for informational purposes only. EyePoint does not guarantee that the use of the recommended codes will result in reimbursement. Providers should always contact the payer directly with reimbursement or billing questions. If you have any questions, please call EyePoint Assist at 1-833-393-7646.


CPT is a registered trademark of the American Medical Association.
Sample UB-04 Paper Claim Form

<table>
<thead>
<tr>
<th>Form locator 4:</th>
<th>Enter the 4-digit code that specifies place of service and submission type. For example, for HOPD, the first 3 digits are 013. The final digit is usually a “1,” meaning one claim for the event.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form locator 17:</th>
<th>Enter Patient Status</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form locator 47:</th>
<th>Enter price for DEXYCU from price schedule, including all applicable markups</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form locator 42*:</th>
<th>Enter the Revenue Code</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form locator 44:</th>
<th>Enter the unique Billing Code for DEXYCU</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form locator 44:</th>
<th>Enter the Procedure Code(s)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form locator 46:</th>
<th>Enter the number of Units. For DEXYCU, 1 unit=1 microgram. Allowable billing for DEXYCU is 517 units</th>
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</table>

<table>
<thead>
<tr>
<th>Form locator 50A:</th>
<th>If Medicare is the primary payer, enter “Medicare” on line A</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Form locator 66:</th>
<th>Enter the primary Diagnosis Code</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Form locator 80:</th>
<th>This is where NDC number should be placed if NOC code required or if Medicaid for 340B rebate requirement</th>
</tr>
</thead>
</table>

*Note: For hospitals and ASCs using the UB-04 form, it is best practice to confirm the correct revenue code with the payer to ensure reimbursement.

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NOC=Not Otherwise Classified.
Resources

Visit www.cms.gov*
- ASC and HOPD Payment Rates and Updates
- CMS Pass-Through Information
- CMS ASP Drug Pricing Files
- MLN Matters®

*This site is not controlled or endorsed by EyePoint and EyePoint is not responsible for the content provided.

Call 1-833-EYEPOINT (1-833-393-7646), option 2, for more information about DEXYCU and EyePoint Assist™

IMPORTANT SAFETY INFORMATION (cont’d)

WARNINGS AND PRECAUTIONS (cont’d)

Exacerbation of Infection
- Fungal infections of the cornea are particularly prone to coincidentally develop with long-term local steroid application and 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
- Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection

Cataract Progression
- The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts

ADVERSE REACTIONS
- The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis

Please see Important Safety Information throughout and accompanying full Prescribing Information.


Information contained in this guide is provided as a reference for obtaining appropriate and accurate reimbursement for the use of DEXYCU in eligible patients. EyePoint does not guarantee reimbursement. EyePoint Assist services are subject to change without notice.

MLN Matters is a registered trademark of the U.S. Centers for Medicare & Medicaid Services.
DEXYCU (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

**WARNINGs AND PRECAUTIONS**

- For intraocular administration (2).
- Administer 0.005 mL of DEXYCU into the posterior chamber inferiorly behind the iris at the end of ocular surgery (2).

**INDICATIONS AND USAGE**

- For intraocular suspension (9% equivalent to dexamethasone 0.1034 mg/mL in a single-dose vial) (2).
- For intraocular administration (2).

**DOSAGE AND ADMINISTRATION**

- Invert the vial.
- Remove the blue plastic flip-cap from the vial and wipe the top of rubber stopper with an alcohol pad.
- Place the syringe ring on the plunger and the 18-gauge needle firmly on contact with the flange of the syringe.
- Remove the needle from the vial and withdrawing the plunger approximately 0.005 mL.
- Insert the needle into the vial and inject enough drug material to fill the syringe. (If the sphere of administered drug after injection volume that will be applied to the patient's eye.)
- Depress the plunger completely and then discard the unused portion in the vial.
- Remove the needle from the vial and discard the unused portion in the vial.
- Hold the syringe vertically with the top of the plunger is the medication chamber.
- Affix the syringe guide over the syringe ring in place.
- Firmly place the cannula on the syringe and remove the plastic cap.
- Hold the syringe vertically with the cannula pointing up.
- Depress the plunger to expel air bubbles from the syringe.
- Depress the plunger with the aid of the plunger guide/ring mechanism comes gently into contact with the flange of the syringe until the plunger guide/ring mechanism comes gently into contact with the flange of the syringe. Lightly tap/tick the barrel of the syringe to remove any excess drug from the tip of the cannula.
- Do not wipe or touch the tip of the cannula to remove excess drug.

**ADVERSE REACTIONS**

- Intraocular suspension: 9% equivalent to dexamethasone 103.4 mg/mL in a single-dose vial provided in a kit (3).

**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).

**HOW SUPPLIED/STORAGE AND HANDLING**

- The DEXYCU administration kit contains the following items:
  1. One glass vial: 0.5 mL of DEXYCU
  2. One sterile 1-mL syringe
  3. One sterile syringe guide
  4. One sterile syringe ring
  5. One sterile 18-gauge needle (1½ inches long), plastic cap attached
  6. One sterile 25-gauge bent cannula (8 mm long), plastic cap attached

**FULL PRESCRIBING INFORMATION: CONTENTS**

- INDICATIONS AND USAGE
- DOSAGE AND ADMINISTRATION
- INTRAOCULAR ADMINISTRATION
- CONTRAINDICATIONS
- WARNINGS AND PRECAUTIONS
- ADVERSE REACTIONS
- USE IN SPECIFIC POPULATIONS
- CLINICAL PHARMACOLOGY
- NONCLINICAL TOXICOLOGY
- CLINICAL STUDIES
- HOW SUPPLIED/STORAGE AND HANDLING

**REFERENCES**

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

**REVISED DATE**

- Revised: 12/2018

**FULL PRESCRIBING INFORMATION: CONTENTS**

- INDICATIONS AND USAGE
  DEXYCU (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation.

- DOSAGE AND ADMINISTRATION
  2.1 Dosing Information
  The dose is 0.005 mL of dexamethasone 9% (equivalent to 517 micrograms).

- CLINICAL PHARMACOLOGY
- NONCLINICAL TOXICOLOGY
- CLINICAL STUDIES
- HOW SUPPLIED/STORAGE AND HANDLING

**REVISIONS**

- Revised: 12/2018

**REFERENCES**

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**REVISED DATE**

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- NONCLINICAL TOXICOLOGY
- CLINICAL STUDIES
- HOW SUPPLIED/STORAGE AND HANDLING

**REVISIONS**

- Revised: 12/2018

**REFERENCES**

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

**REVISED DATE**

- Revised: 12/2018
3 DOSE FORMS AND STRENGTHS

DEXYCU contains dexamethasone 9% w/w (10.4 mg/mL) as a sterile suspension for intraocular ophthalmic administration. DEXYCU is provided as a kit for administration of a single dose of 0.056 mL of 9% dexamethasone (equivalent to 0.175 milligrams of dexamethasone).

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Increase in Intraocular Pressure

Prolonged use of corticosteroids including DEXYCU may result in glaucoma with damage to the optic nerve, defects in visual acuity and field of vision. Stenotic should be used with caution in the presence of glaucoma.

5.2 Delayed Healing

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In these diseases causing thinning of the cornea or iris, perforations have been known to occur with the use of corticosteroids.

5.3 Exacerbation of Infection

The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of any acute viral disease of the cornea and conjunctiva including viral keratitis simplex keratitis (herpetic keratitis), vaccinia, and varicella, and in mycobacterial infections of the cornea and conjunctiva.

Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires caution. Use of ophthalmic steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Fungal infections of the cornea are particularly prone to develop coincidentally with long-term topical steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a herpes has been used or is in use. Fungal culture should be taken when appropriate.

Prolonged use of corticosteroids may suppress the host response and thus increase the risk of secondary bacterial infections. In such patients condition, steroids may mask infection or enhance existing infection.

5.4 Cataract Progression

Use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts.

6 ADVERSE REACTIONS

The following adverse reactions are described elsewhere in the labeling:

• Increase in Intraocular Pressure (see Warning and Precautions 5.1)
• Delayed Healing (see Warnings and Precautions 5.2)
• Infection Exacerbation (see Warnings and Precautions 5.3)
• Cataract Progression (see Warnings and Precautions 5.4)

6.1 Clinical Trials Experience

Because clinical studies 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 studies of another drug and may not reflect the rates observed in practice.

The following adverse events rates are derived from three clinical trials in which 339 patients received the 51.7 microgram dose of DEXYCU. The most commonly reported adverse reaction occurred in ≤5% of subjects and included increases in intraocular pressure, corneal edema and iritis. Other ocular adverse reactions occurring in ≤5% of subjects included, corneal endothelial cell loss, blepharitis, eye pain, postoperative band keratopathy, dry eye, ocular inflammation, posterior capsular opacification, blurred vision, photophobia, foreign body sensation, photophobia, and vitreous detachment.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled studies of DEXYCU (dexamethasone intraocular suspension) 9% in pregnant women. Topical ocular administration of dexamethasone in mice and rabbits during the period of organogenesis produced cleft palate and embryonal death in mice and malformations of abdominal wall and intestines in rabbits at doses of 1 and 5 times higher than the injected recommended humanopharmaceutical dose (800 μg) of DEXYCU (51.7 micrograms dexamethasone), respectively (see Data).

In the US general population the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15 to 20%, respectively.

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, opalescent suspension for intraocular administration. Each vial of DEXYCU contains 0.5 mL of 9% w/w dexamethasone suspension equivalent to 0.5 mg of dexamethasone. The inactive ingredient is acetyl triethyl citrate. DEXYCU does not contain an antimicrobial preservative.

The chemical name of dexamethasone is pregn-1-ene-3,21-dione-21,20-dione, 9-fluor-11,17,21-trihydroxy-16- methyl, (11β,16α). It has a molecular formula of C₂₃H₃₇FO₅ and a molecular weight of 392.46 grams per mole. Its structural formula is:

8.12 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 of 9% of dexamethasone at the end of cataract surgery. Blood samples were collected prior to surgery and at Central time points post-surgery between Day 0 and up to Day 10. In the first study, the dexamethasone plasma concentrations on post-surgery Day 1 ranged from 0.09 to 0.06 mg/mL and from 0.07 to 0.16 mg/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 0.149 to 0.29 mg/mL, following administration of DEXYCU 517 mg. 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).

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.

14 CLINICAL STUDIES

Clinical efficacy was evaluated in a randomized, double-masked, placebo-controlled trial (NCT02066898) in which subjects received either DEXYCU or placebo (vehicle). A dose of 5 microliters of DEXYCU (equivalent to 517 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 1P). The presence of an anterior chamber cell was assessed using a sterile lamp biomicroscope up to 10 days post-surgery. The treatment of patients with anterior chamber clearing at Day 8 was 20% in the placebo group, and 57% and 69% in the 342 and 517 microgram treatment groups, respectively (Table 1). The percentage of subjects receiving rescue medication of ocular steroids or NSAIDs was significantly lower at Day 8, 1, 3 and 10 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>Placebo</th>
<th>DEX342</th>
<th>DEX517</th>
<th>DEX342 vs Placebo</th>
<th>DEX517 vs Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 8</td>
<td>20% (4)</td>
<td>28% (4)</td>
<td>57% (4)</td>
<td>10% (0)</td>
<td>37% (0)</td>
</tr>
<tr>
<td>Day 3</td>
<td>13% (3)</td>
<td>21% (4)</td>
<td>29% (4)</td>
<td>2% (0)</td>
<td>18% (0)</td>
</tr>
<tr>
<td>Day 1</td>
<td>12% (3)</td>
<td>24% (4)</td>
<td>36% (4)</td>
<td>1% (0)</td>
<td>25% (0)</td>
</tr>
</tbody>
</table>

Subjects who received rescue medication were treated as failures.

Table 2: Proportion of subjects receiving 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</td>
<td>DEX342 vs Placebo</td>
</tr>
<tr>
<td>Day 8</td>
<td>20% (4)</td>
</tr>
<tr>
<td>Day 3</td>
<td>13% (3)</td>
</tr>
<tr>
<td>Day 1</td>
<td>12% (3)</td>
</tr>
</tbody>
</table>