

**United States Food and Drug Administration****Consumer Complaint / Injury Report**

This is an accurate reproduction of the original electronic record as of 04/17/2023

**COMPLAINT** | # **179082**

<b>Complaint Date</b>	<b>Receiving Organization</b>	<b>Accomplishing District</b>	<b>How Received</b>	<b>Complaint Source</b>	<b>Complaint Received By</b>	<b>Complaint Status</b>
02/10/2023	DAL-DO	NWJ-DO	Telephone	Consumer	Tate, Leon P	(b) (5)

**Complainant Identification**

<b>Name</b>	<b>Address</b>
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(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)
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<b>Phone (W)</b>	<b>Phone (H)</b>	<b>Source POC Name</b>	<b>Source Phone</b>
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(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)		
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**Complaint/Injury**

<b>Complaint Description</b>	<b>Adverse Event Result</b>	<b>Adverse Event Date</b>	<b>Injury / Illness</b>
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02.10.23 Complainant voice message state: She is calling about the Ezricare artificial tears lubricant eye drops which she was using. She received the product from (b) (6), and heard about the Ezricare Recall on the news. She reports having an adverse incident but did not state her reactions. She is calling to ask what are the symptoms, and requested a return phone call.

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02.14.23 DAL-DO CCC: Complainant states she purchased Ezricare artificial tears lubricant eye drops product from (b) (6) In March 2022, she purchased a pack which contained 2 bottles. In September 2022, she purchased another pack which contained 2 bottles.

She had (unrelated) cataract surgery in (b) (6), (b) (7)(C) and was not using the artificial tears lubricant eye drops daily.

On or about 10 December 2022, she began noticing symptoms of itchy and irritated eyes, did not attribute it to the use of the product at that time.

On 15 December 2022, symptoms of eyes irritation and pain got worse. She visited her primary care doctor with symptoms of constant eye pain, gup on eyelids, eyes sore to the touch, and small pimple growing underneath right eyelid.

She was diagnosis with blepharitis, received a prescription for Erythromycin eye ointment, and experienced relief after a week of use.

Complainant states the irritation and pain has subsided. She still has minor pain near both eye sockets, pain is stronger in her right eye, and rubbing her eye lids still cause minor irritation

On 1 February 2023 she received email Recall notification from (b) (6) informing her to stop use of Ezri Care Artificial Tears product - She stopped use of product in December 2022.

She has completely used 2 bottles of artificial tears lubricant eye drops.

Remaining - she has 1 unopen sealed bottle, and 1 open bottle containing 7 MI artificial tears lubricant eye drops.

Non-Life Threatening Injury/Illness - No Adverse Event Reporting
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12/10/2022
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Other - identify in Remarks
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Notify OEO?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/10/2023	Yes	No	Yes	Not Report to Other Source	Unknown

**Remarks**

itchy eyes, eye irritation and pain, gup on eyelids, eyes sore to the touch, and small pimple growing underneath right eyelid

**Complaint Symptoms**

Symptom	System Affected	Onset Time	Duration	Remarks
Eye irritation	NERVOUS	Months		
NEC - Identify in Remarks	NEC			itchy eyes, and pain, gup on eyelids, eyes sore to the touch, and small pimple growing underneath right eyelid

**Health Care Professional**

Provider Name	Address	Phone	Occupation
(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)		Primary Care Doctor

**Hospital Information**

Hospital Name	Address	Phone	Dates of Stay

**Emergency Room/Outpatient Visit**

Hospital Name	Address	Phone	ER Date
(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)	(b) (7)(C), (b) (6)

**Product and Labeling**

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
Ezricare	tears, artificial lubricant eye drops	64DBY01	Carboxymethylcellulose Sodium, Emollient,Lubricant;Human - Non/Rx Combination Ingredient;NEC	56R801	not provided ye

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
15 Milliliters Bottle	PCMJ014	Mar 2025	03/2022 and 09/2022	Yes	7 Ml

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
march 2022	12.10.22	8 MI and 1 unopen	Yes	India	79503-0101-15*** U.S. Distributor as EzriRx, 2360 Rt 9, Suite 3 #171, Toms River, NJ 08755 (Phone: 718-502-6610)  Distributed by EzriCare LLC Lakewood NJ Ezricare.com

**Retail**

Name	Address
(b) (6)	

**Problem Ingredient Group****Manufacturer/Distributor**

FEI	Name & Address	Home District	Firm Type
3012323885	Global Pharma Healthcare Private Limited A - 9 Sidco Pharmaceutical Complex Thiruporur Chennai India 603110	ORAHQ	Manufacturer
(b) (4)	(b) (4)	NYK-DO	Importer
3022210898	EzriCare, LLC. 1525 Prospect St Ste 204 Lakewood New Jersey United States 08701-4662	NWJ-DO	Distributor

**Initial Evaluation/Initial Disposition**

Problem Keyword	Problem Keyword Details
Reaction	Itchy, irritated eye pain, gup on eyelids, eyes sore, pimple underneath right eyelid
Other, identify in Details	RES 91621

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	(b) (5)	Price,Linda L	02/21/2023

**Initial Disposition Remarks**

02.10.23 DAL-DO CCC: Called consumer, no answer left voice message with name, CCN, and dalcc@fda.hhs.gov email address. Manufacturer verification provided by NCCC Sheila Van Twuyler email: Ezri Care Artificial Tears Complaints Guidance 2/1/2023.

02.14.23 DAL-DO CCC: NEW\*\* All EzriCare eye drop complaints should list the U.S. Distributor as EzriRx, 2360 Rt 9, Suite 3 #171, Toms River, NJ 08755 (Phone: 718-502-6610) Currently no FEI #. provided by NCCC Sheila Van Twuyler

02.14.23 DAL-DO CCC: Called consumer, she has half a bottle of the product remaining, unable to locate it during our phone call.

02.14.23 DAL-DO CCC: Please refer EzriCare complaints to NWJ-DO as Accomplishing District. Please document the FEI for the Distributor: EzriRx/EzriCare, NJ (FEI 3022210898).

Please keep Importer as (b) (4) and in remarks indicate the importer in NY is OOB. V/r, Sheila

02.15.23 DAL-DO CCC: Complaint forward to NWJ-DO  
2/21/2023 NWJ-DO EzriCare Recall 91621. Date of Recall 2/2/2023. Emailing Nerizza Guerin, DIB PHARM 1, William Muszynski, ERC. Dispositioning to (b) (5) per Sheila Vantwuyver, NCCC.

**Referrals**

<b>Org Name</b>	<b>HHS Mail Code</b>
ORAHQ	HFC-1
NYK-DO	HFR-NE100
PHRM2	PHRM2
NWJ-DO	HFR-MA300

**There are no Cosmetics details for this Complaint.**

**There are no Adverse Event details for this Complaint.**

**Related Complaints**

**COMPLAINTS FOLLOW - UP****Grouped Follow - Up Operations**

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
11859504	13	12271954	PHRM1	PHRM1-2-G3			Completed	02/23/2023

**Disposition Summary**

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
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Follow-Up Disposition	Disposition Made By	Disposition Date
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**Disposition Remarks****Follow-Up Sent To**

Organization Name	HHS Mail Code
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