Eohilia™
(budesonide oral suspension) 2mg

FIRST AND ONLY FDA-APPROVED oral treatment for EoE for 12-week use in patients 11 years and older. EOHILIA has not been shown to be safe and effective for longer than 12 weeks.[1]

DESIGNED FOR EoE

One of the largest clinical programs of EoE in the U.S.

The efficacy and safety of EOHILIA 2 mg twice daily was evaluated in 410 patients 11-56 years of age with EoE across 2 multicenter, randomized, double-blind, parallel-group, placebo-controlled 12-week studies.[1]

Key Inclusion Criteria[1-3]

- Esophageal inflammation, defined as peak eosinophil count ≥15/hpf from at least 2 levels of the esophagus
- ≥4 days of dysphagia over a 2-week period, as measured by the DSQ
- Non-responsiveness to high-dose PPI therapy for ≥6 weeks

Key Exclusion Criteria[1-3]

- Use of swallowed topical corticosteroids for EoE or systemic corticosteroids for any condition ≤4 weeks before screening
- Pure liquid or six-food elimination diet (SFED)
- Use of CYP3A4 inhibitors
- Presence of a high-grade esophageal stricture

Proven effective in achieving histologic remission as well as reduction in frequency and severity of dysphagia after 12 weeks[1,4]*

STUDY 1

Greater proportion of patients achieved histological remission with EOHILIA vs placebo
(defined as a peak eosinophil count of ≤6/hpf across all available esophageal levels)[1]

53% EOHILIA 2 mg b.i.d. (n=213) **vs** **1%** placebo (n=105)

Δ52.4%† (95% CI: 43.3, 59.1)

Greater reduction in DSQ combined score with EOHILIA vs placebo
Absolute change from baseline in DSQ combined score (0-84‡) LS, mean (SE)[1]

-10.2 pt **(1.5)** EOHILIA 2 mg b.i.d. (n=213) **vs** **-6.5** pt **(1.8)** placebo (n=105)

Δ-3.7† (95% CI: -6.8, -0.6)

STUDY 2

Greater proportion of patients achieved histological remission with EOHILIA vs placebo
(defined as a peak eosinophil count of ≤6/hpf across all available esophageal levels)[1]

38% EOHILIA 2 mg b.i.d. (n=50) **vs** **2.4%** placebo (n=42)

Δ35.8%† (95% CI: 17.2, 50.0)

Greater reduction in DSQ combined score with EOHILIA vs placebo
Absolute change from baseline in DSQ combined score (0-84‡) LS, mean (SE)[1]

-14.5 pt **(1.8)** EOHILIA 2 mg b.i.d. (n=50) **vs** **-5.9** pt **(2.1)** placebo (n=42)

Δ-8.6† (95% CI: -13.7, -3.5)

The mean (SD) peak eosinophil counts at baseline for Study 1: 74.5 (39.2) and 76.6 (45.0) in the EOHILIA and placebo groups, respectively. For Study 2: 157.8 (96.1) and 133.0 (81.6) in the EOHILIA and placebo groups, respectively.[5,6] The mean (SD) DSQ combined scores at baseline for Study 1: 30.3 (13.9) and 30.4 (13.1) in the EOHILIA vs placebo groups, respectively. For Study 2: 30.7 (16.0) and 29.0 (13.5) in the EOHILIA and placebo groups, respectively.[1]

*As measured by DSQ.[1]

†For histological remission, the difference in percentages and 95% Newcombe confidence intervals are estimated using Mantel Haenszel weights, adjusting for age group and diet restriction. For absolute change in DSQ score, the LS mean changes, standard errors, and differences are estimated using an ANCOVA model with treatment group, age group, diet restriction, and baseline measurement as covariates.[1]

‡Total biweekly DSQ scores range from 0 to 84; higher scores indicate greater frequency and severity of dysphagia.[1]

b.i.d.=twice daily; CI=confidence interval; DSQ=Dysphagia Symptom Questionnaire; LS=least squares; PPI=proton pump inhibitor; SD=standard deviation; SE=standard errors.

INDICATION AND LIMITATIONS OF USE

EOHILIA (budesonide oral suspension) is indicated for 12 weeks of treatment in patients 11 years and older with eosinophilic esophagitis (EoE).

EOHILIA has not been shown to be safe and effective for more than 12 weeks.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

EOHILIA is contraindicated in patients with hypersensitivity to budesonide. Serious hypersensitivity reactions, including anaphylaxis, have occurred with oral budesonide products.

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DESIGNED FOR EoE

Established safety profile

The safety of EOHILIA in 410 adult and pediatric patients 11-56 years of age with EoE was evaluated in 2 double-blind, placebo-controlled studies for 12 weeks.[1]

Study 1: Common Adverse Reactions[1]
Reported in at least 2% of patients taking EOHILIA and at a rate greater than in those taking placebo

Adverse reactions	EOHILIA 2 mg twice daily n=213	Placebo n=105
Respiratory tract infection includes acute sinusitis, sinusitis, nasopharyngitis, respiratory tract infection, respiratory tract infection viral, upper respiratory tract infection, viral upper respiratory tract infection, rhinitis	13%	11%
Gastrointestinal mucosal candidiasis includes esophageal candidiasis, oropharyngeal candidiasis, oral candidiasis	8%	2%
Headache includes migraine	5%	2%
Gastroenteritis	3%	1%
Sore throat includes throat irritation, oropharyngeal pain	3%	2%
Adrenal suppression includes adrenal suppression, adrenal insufficiency	2%	0%
Erosive esophagitis includes esophagitis only where erosions were present at the esophagogastroduodenoscopy conducted after 12 weeks of treatment	2%	0%

The safety profile of EOHILIA in Study 2 was generally similar to Study 1.[1]

To report SUSPECTED ADVERSE REACTIONS, call the FDA at 1-800-FDA-1088, or visit www.fda.gov/medwatch

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Hypercorticism and Adrenal Axis Suppression

Monitor patients for signs and symptoms and consider reducing the EOHILIA dosage. Use is not recommended in severe hepatic impairment (Child-Pugh Class C). Monitor for hypercorticism in moderate hepatic impairment (Child-Pugh Class B). Where patients are subject to stress situations (e.g., trauma, surgery, infection) supplementation with a systemic corticosteroid is recommended.

Please click here for full Prescribing Information.

Patient Portrayal

Discontinued his swallowed aerosol steroid

Meet Mike, 35

A patient with EoE who is currently experiencing ongoing symptoms

"I struggled with swallowing something that is meant to be inhaled and would like to explore another oral option—one that's FDA approved for EoE."

Diagnosed: 4 years ago

Comorbidities: Asthma, allergic rhinitis (controlled)

Previous therapy: Stopped taking swallowed steroid aerosols 4 weeks ago, used to take PPIs, and has used diet modification (restricted eggs, wheat, milk products)

Current presentation: Still seeking relief from his EoE symptoms

Clinical history

- EoE diagnosis confirmed 4 years ago by a gastroenterologist based on
  - **Symptom complaints:** Dysphagia several times a week
  - **Histological findings:** Peak eosinophil count 65 eos/hpf
  - Endoscopic findings: Proximal rings and furrows with presence of exudates

Notes from patient

- Reports excessive chewing, avoiding meals out with friends, and needing to drink water to relieve dysphagia symptoms several times in the last month
- Comfortable with oral therapies and wants to try an oral option specifically intended for EoE

Is there an oral, FDA-approved option for EoE available for Mike?

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Immunosuppression and Increased Risk of Infection

Corticosteroid-associated infections can be mild, severe, and at times fatal. Monitor patients and consider discontinuation if infection develops.

- **Tuberculosis and Hepatitis B Virus (HBV) reactivation may occur.** Closely monitor EOHILIA patients. Screen for HBV.
- **Varicella Zoster (VZ) and Measles** can be serious or fatal. Avoid exposure. If a patient is exposed to varicella, consider prophylaxis with VZ immune globulin (IG); if varicella develops, consider antiviral treatment. If a patient is exposed to measles, consider prophylaxis with IG.
- **Rule out amebiasis** before starting EOHILIA in patients who were in the tropics or have unexplained diarrhea.

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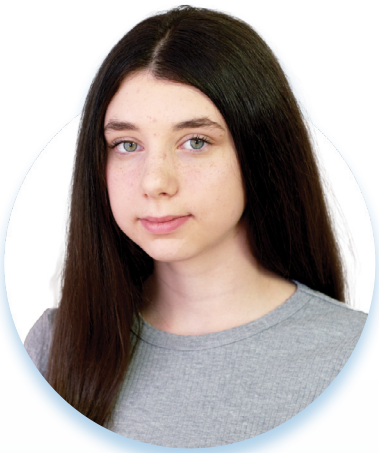

Patient Portrayal

Failed to control EoE symptoms with diet modification

Meet Kiana, 11

A pediatric patient who hasn't found an EoE treatment strategy that works for her

"Our daughter is starting to avoid eating at all. We are sensitive to her age and want a treatment that she could eventually learn to manage on her own as she becomes more independent."

Diagnosed: 2 years ago

Comorbidities: Peanut allergy

Previous therapy: Diet modification (restricted seafood, wheat) prescribed 3 months ago

Current presentation: Struggling with diet modification therapy and still experiencing EoE symptoms daily

Clinical history

- Suspected EoE after her mother noticed she was avoiding solid foods
- Diagnosis was confirmed by pediatric gastroenterologist 2 years ago based on
  - **Symptom complaints (unsure of when they started):** Choking and gagging with certain foods once a day; dysphagia once a day
  - **Histological findings:** Peak eosinophil count 47 eos/hpf
  - Endoscopic findings: Proximal stricture as well as edema and exudates in distal esophagus

Notes from patient

- Her parents report that Kiana eats very little; she cuts food into small pieces, chews excessively, and drinks water with most bites of food
- Kiana and her family would prefer a premixed oral option, one she can take with her on the go

Is there a premixed treatment that both Kiana and her parents would consider?

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Immunosuppression and Increased Risk of Infection (continued)

- **Avoid EOHILIA in patients with:** systemic fungal infections, known or suspected Strongyloides infection, cerebral malaria, and active ocular herpes simplex.
- **Localized Infections:** In clinical trials, some patients developed *Candida albicans* infections in the mouth, throat, and esophagus. Instruct patients: do not eat or drink for 30 minutes after taking EOHILIA; after 30 minutes rinse mouth with water and spit without swallowing. Treat candidiasis infections with appropriate antifungal therapy and consider discontinuing EOHILIA.

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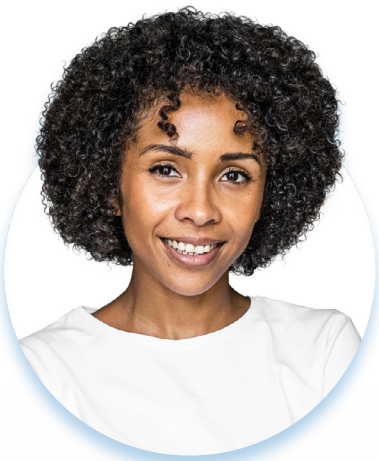
Previous slurry user



Patient Portrayal

Meet Jackie, 41

A previous slurry user looking for another oral treatment option

"I can't find a treatment that fits in my daily routine. I'm a busy working parent, and every minute matters."

Diagnosed: 6 years ago

Comorbidities: None

Previous therapy: Stopped steroid slurries and PPIs 1 month ago; has used diet modification (restricted peanuts, milk products, eggs)

Current presentation: She was uncomfortable mixing steroid slurries and found it difficult to comply with her treatment. She is seeking another treatment option

Clinical history

- Diagnosed after experiencing food impaction requiring emergency medical attention
- Diagnosis confirmed by her gastroenterologist based on
  - **Symptom complaints (on and off for more than 3 years):** Dysphagia at almost every meal and food impaction a few times a week
  - **Histological findings:** Peak eosinophil count 102 eos/hpf
  - Endoscopic findings: Proximal esophageal stricture as well as distal rings and furrows
- 2 prior esophageal dilations

Notes from patient

- Complains about time it takes to make slurries and reports that, consequently, she'd miss doses

Is there a different way for Jackie to manage her EoE?

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Erosive Esophagitis

Patients who experienced erosive esophagitis in clinical trials did not have erosions at baseline and most were receiving a proton pump inhibitor. Advise patients or caregivers to report new onset or worsening of erosive esophagitis to their healthcare provider. Consider endoscopic evaluation.

Symptoms of Steroid Withdrawal in Patients Transferred from Other Systemic Corticosteroids

Adrenocortical function monitoring may be required in patients who are transferred from high systemic effects corticosteroids to EOHILIA, since symptoms attributed to withdrawal of steroid therapy, including those of acute adrenal axis suppression or benign intracranial hypertension, may develop.

Taper slowly from high systemic effects corticosteroids. Replacing systemic corticosteroids with EOHILIA may unmask previously controlled allergies (e.g., rhinitis and eczema).

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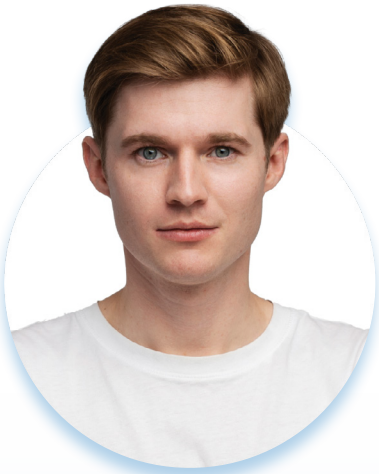
Steroid-naïve EoE patient

Meet Luke, 25



Patient Portrayal

A newly diagnosed, steroid-naïve EoE patient

"Now that I finally understand my condition, I want to know what options I have for treatment. I hope to find a treatment specifically for my EoE that fits into my busy life."

Diagnosed: 8 months ago

Comorbidities: None

Previous therapy: Has been on a stable dose of PPIs for the past month; has used diet modification (restricted wheat and meat)

Current presentation: Despite a recent trial of PPI therapy, reports persistent EoE symptoms

Clinical history

- His primary care physician (PCP) referred him to an allergist, who then referred him to a gastroenterologist for evaluation of dysphagia symptoms that increase when eating
- Diagnosis was confirmed based on
  - **Symptom complaints (less than a year):** Vomiting to relieve dysphagia symptoms a few times a week
  - **Histological findings:** Peak eosinophil count 72 eos/hpf
  - Endoscopic findings: Exudates in the proximal esophagus, distal rings, and edema

Notes from patient

- Avoids hard or lumpy foods and large meals
- For his busy lifestyle, he wants to find an oral treatment option that does not need to be refrigerated

Is there a treatment option available for Luke that doesn't require refrigeration?

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Other Corticosteroid Effects

Monitor patients with or family history of: hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, or cataracts or with other conditions where corticosteroids may have unwanted effects.

Additional Established Class Effects of Corticosteroids not seen in EOHILIA 12-week clinical trials. The maximum recommended duration of treatment with EOHILIA is 12 weeks:

- **Effect on Growth:** Use of corticosteroids may cause a reduction of growth velocity. Monitor the growth of pediatric patients on EOHILIA.
- **Kaposi's Sarcoma:** Reported to occur with corticosteroids, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma.

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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ADVERSE REACTIONS

Most common adverse reactions (≥2%) are: respiratory tract infection (13%), gastrointestinal mucosal candidiasis (8%), headache (5%), gastroenteritis (3%), throat irritation (3%), adrenal suppression (2%), and erosive esophagitis (2%).

DRUG INTERACTIONS

Avoid concomitant use with CYP3A4 inhibitors (including grapefruit juice), which can increase systemic budesonide concentrations.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Hypoadrenalism may occur in infants whose mothers received corticosteroids during pregnancy. Carefully observe infants for hypoadrenalism and manage accordingly.
- **Lactation:** Lactation studies have not been conducted. Consider the benefits of breastfeeding, the mother's need for EOHILIA, and any potential adverse effects on the infant from EOHILIA, or from the underlying maternal condition.
- **Hepatic Impairment:** Not recommended in severe hepatic impairment (Child-Pugh Class C). Monitor for hypercorticism in moderate hepatic impairment (Child-Pugh Class B).

References: 1. EOHILIA (budesonide oral suspension) Prescribing Information. Takeda Pharmaceuticals, Inc. **2.** ClinicalTrials.gov identifier NCT02605837. November 16, 2015. Updated June 8, 2021. Accessed January 31, 2024. https://classic.clinicaltrials.gov/ct2/show/NCT02605837. **3.** Data on file, Takeda Pharmaceuticals, Inc. **4.** Hudgens S, Evans C, Phillips E, et al. *J Patient Rep Outcomes.* 2017;1(1):3. **5.** Hirano I, Collins MH, Katzka DA, et al. *Clin Gastroenterol Hepatol*. 2022;20(3):525-534.e10. **6.** Dellon ES, Katzka DA, Collins MH, et al. *Gastroenterology*. 2017;152(4):776-786.e5.

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If you are a Connecticut prescriber, please see the Connecticut WAC disclosure form.