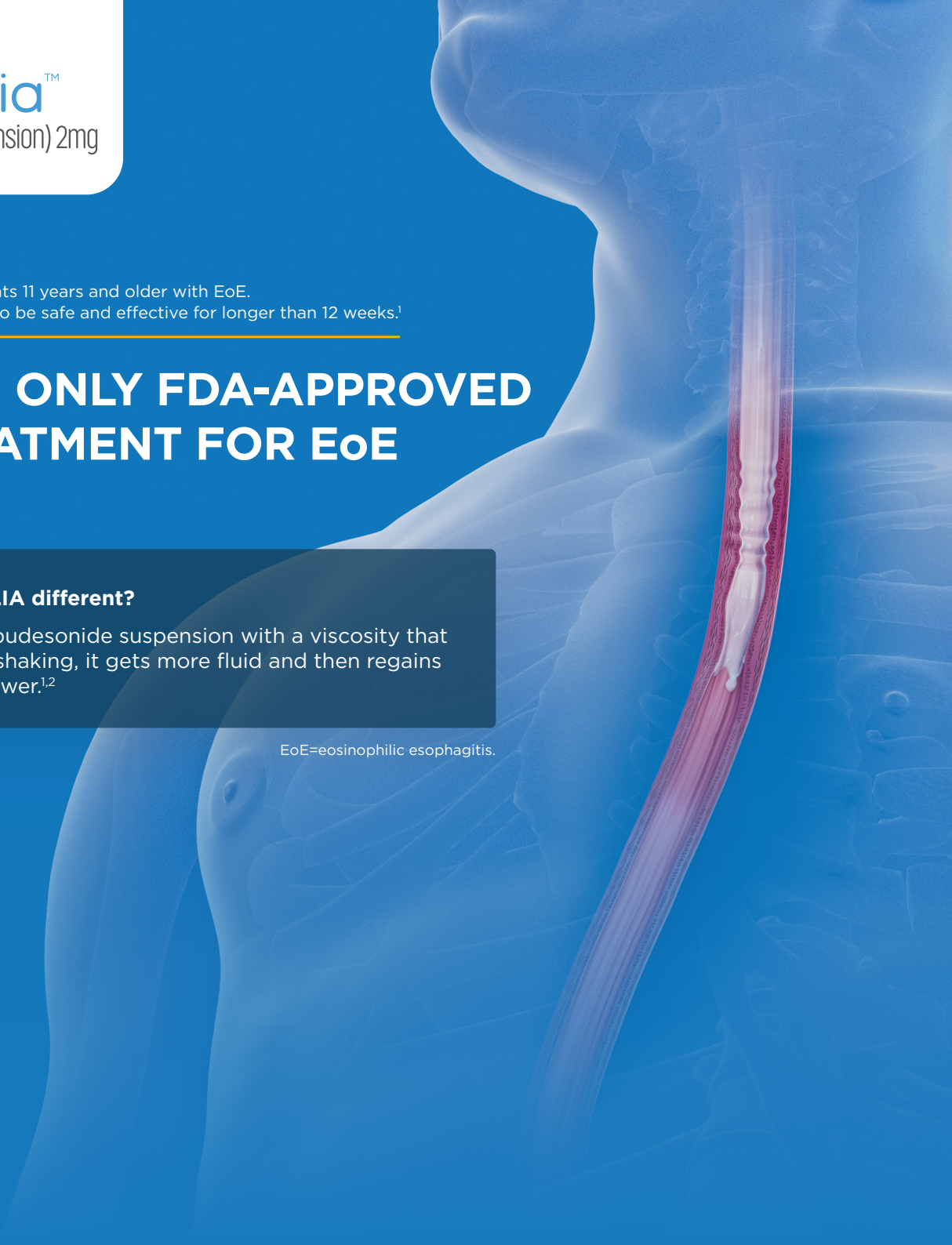
Eohilia™
(budesonide oral suspension) 2mg

A 12-week treatment for patients 11 years and older with EoE.
EOHILIA has not been shown to be safe and effective for longer than 12 weeks.[1]

FIRST AND ONLY FDA-APPROVED ORAL TREATMENT FOR EoE

What makes EOHILIA different?

EOHILIA is an oral budesonide suspension with a viscosity that can change—upon shaking, it gets more fluid and then regains viscosity to flow slower.[1,2]



EoE=eosinophilic esophagitis.

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

EOHILIA has not been shown to be safe and effective for the treatment of EoE for longer 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.

Please see additional Important Safety Information throughout and on pages 5 and 6. Please click here for full Prescribing Information.

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[1,3,4]

- 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[1,3,4]

- 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*[1,5]

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.[6,7] 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=Dysphasia Symptom Questionnaire; LS=least squares; PPI=proton pump inhibitor; SD=standard deviation; SE=standard errors.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Hypercorticism and Adrenal Axis Suppression

Systemic effects such as hypercorticism and adrenal axis suppression may occur. Monitor patients for signs and symptoms and consider reducing the dosage of EOHILIA. Use is not recommended in patients with severe hepatic impairment (Child-Pugh Class C) and monitoring for signs and/or symptoms of hypercorticism is recommended in patients with moderate hepatic impairment (Child-Pugh Class B).

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Eohilia™ (budesonide oral suspension) 2mg

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

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Eohilia™ (budesonide oral suspension) 2mg

Consistent dosing + portability

- EOHILIA is available in premixed, 2 mg/10 mL single-dose stick packs to help ensure consistent dosing of budesonide. No mixing or measuring required[1]
- Does not have to be refrigerated and can be stored at room temperature (36°F to 77°F) for on-the-go use. Excursions up to 86°F are acceptable. Do not freeze[1]
- Recommended dosage of EOHILIA for patients 11 years and older is 2 mg/10 mL orally twice daily for 12 weeks[1]

4-step administration summary

STEP 1

Do not take with food or liquid[1]

Do not mix EOHILIA with food or liquid[1]

STEP 2

Shake stick pack for at least 10 seconds[1]

STEP 3

Squeeze until the EOHILIA stick pack is empty. Swallow all the EOHILIA suspension[1]

STEP 4

Wait 30 min before eating or drinking. Then rinse mouth with water and spit out contents without swallowing[1]

Avoid drinking grapefruit juice during treatment with EOHILIA.[1]

This is not all the information needed to administer EOHILIA. Please click here to see Instructions for Use included in full Prescribing Information.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Hypercorticism and Adrenal Axis Suppression (continued)
Corticosteroids, including EOHILIA, can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to trauma, surgery, infection, or other stress situations, supplementation with a systemic corticosteroid is recommended.

Please see additional Important Safety Information throughout and on pages 5 and 6. Please click here for full Prescribing Information.

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IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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WARNINGS AND PRECAUTIONS

Hypercorticism and Adrenal Axis Suppression

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Corticosteroids, including EOHILIA, can reduce the response of the hypothalamus-pituitary-adrenal (HPA) axis to stress. In situations where patients are subject to trauma, surgery, infection, or other stress situations, supplementation with a systemic corticosteroid is recommended.

Immunosuppression and Increased Risk of Infection

Corticosteroids, including EOHILIA, suppress the immune system and increase the risk of infection with any pathogen. Corticosteroid-associated infections can be mild, severe, and at times fatal. Monitor patients and consider discontinuation of EOHILIA if the patient develops an infection.

- **Tuberculosis reactivation may occur.** Closely monitor patients with latent tuberculosis or tuberculin reactivity while receiving EOHILIA.
- **Varicella Zoster and Measles** can be serious or fatal in non-immune patients taking corticosteroids. Avoid exposure. If a patient is exposed to varicella, prophylaxis with varicella zoster immune globulin may be indicated. If varicella develops, treatment with antiviral agents may be considered. If a patient is exposed to measles, prophylaxis with immunoglobulin may be indicated.
- **Hepatitis B Virus Reactivation can occur.** Prior to starting EOHILIA for patients who show evidence of hepatitis B infection, recommend consultation with physicians with expertise in managing hepatitis B regarding monitoring and consideration for hepatitis B antiviral therapy.
- **Amebiasis:** It is recommended that latent or active amebiasis be ruled out before starting EOHILIA in patients who have spent time in the tropics or have unexplained diarrhea.
- **Avoid EOHILIA in patients with:** systemic fungal infections, known or suspected Strongyloides (threadworm) 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. If oropharyngeal or esophageal candidiasis develops, treat with appropriate antifungal therapy and consider discontinuing EOHILIA.

Erosive Esophagitis

Erosive esophagitis occurred in subjects who received EOHILIA in a 12-week clinical trial. None of the subjects had erosions at baseline esophagogastroduodenoscopy (EGD), and most were receiving concomitant therapy with a proton pump inhibitor (PPI). Advise patients or caregivers to report new onset or worsening signs or symptoms of erosive esophagitis to their healthcare provider. Consider endoscopic evaluation as appropriate.

Effect on Growth

Use of corticosteroids may cause a reduction of growth velocity in pediatric patients. Monitor the growth of pediatric patients on EOHILIA. The maximum recommended duration of treatment with EOHILIA is 12 weeks.

continued on next page

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Symptoms of Steroid Withdrawal in Patients Transferred from Other Systemic Corticosteroids

Monitor patients who are transferred from corticosteroids with high systemic effects to corticosteroids with lower systemic availability, such as EOHILIA, since symptoms attributed to withdrawal of steroid therapy, including those of acute adrenal axis suppression or benign intracranial hypertension, may develop. Adrenocortical function monitoring may be required in these patients and the dose of corticosteroid treatment with high systemic effects should be reduced cautiously. Replacement of systemic corticosteroids with EOHILIA may unmask allergies (e.g., rhinitis and eczema) previously controlled by the systemic drug.

Other Corticosteroid Effects

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

Kaposi's Sarcoma

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid therapy, most often for chronic conditions. Discontinuation of corticosteroids may result in clinical improvement of Kaposi's sarcoma. The maximum recommended duration of treatment with EOHILIA is 12 weeks.

ADVERSE REACTIONS

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

DRUG INTERACTIONS

Budesonide is a substrate for CYP3A4. Avoid concomitant use with CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, erythromycin, cyclosporine, and grapefruit juice), which can increase systemic budesonide concentrations.

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Hypoadrenalism may occur in infants born of mothers receiving corticosteroids during pregnancy. Infants should be carefully observed for signs of hypoadrenalism and managed accordingly.
- **Lactation:** Lactation studies have not been conducted with EOHILIA. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EOHILIA and any potential adverse effects on the breastfed infant from EOHILIA, or from the underlying maternal condition.
- **Hepatic Impairment:** Not recommended in patients with severe hepatic impairment (Child-Pugh Class C). In patients with moderate hepatic impairment (Child-Pugh Class B), monitor for signs and/or symptoms of hypercorticism.

Indication and Limitations of Use

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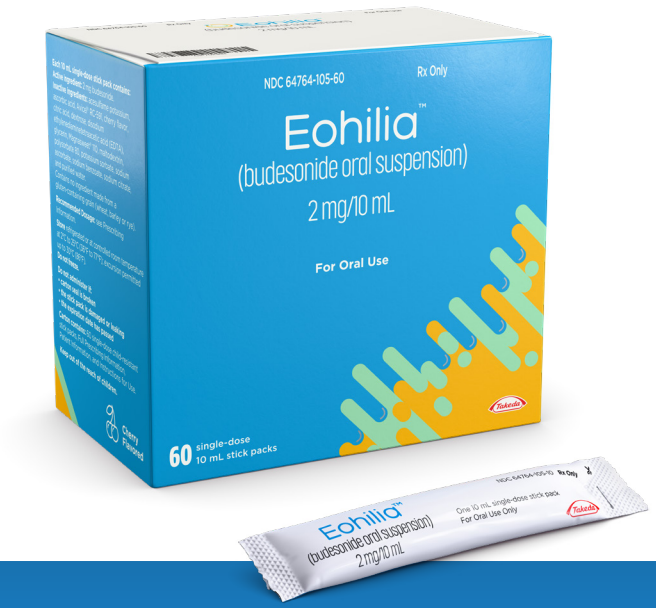
EOHILIA is a 12-week treatment for patients 11 years and older with eosinophilic esophagitis (EoE). It is not known if EOHILIA is safe or effective beyond 12 weeks.[1]

FIRST AND ONLY FDA-APPROVED ORAL TREATMENT FOR EoE

Shake-responsive viscosity
EOHILIA is designed as a viscous suspension to enable it to get more fluid when shaken, and then returns to its initial state.[1,2]

Proven efficacy + established safety profile
Efficacy and safety were evaluated in first phase 3 clinical trial of EoE in the U.S.[1,6]

Reliable dosing + portable
Premixed stick packs ensure consistent budesonide dosing and offer on-the-go use.[1]



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

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

References: 1. EOHILIA (budesonide oral suspension) Prescribing Information. Takeda Pharmaceuticals, Inc. **2.** Lee CH, Moturi V, Lee Y. *J Control Release.* 2009;136(2):88-98. **3.** ClinicalTrials.gov identifier NCT02605837. November 16, 2015. Updated June 8, 2021. Accessed January 31, 2024. https://classic.clinicaltrials.gov/ct2/show/NCT02605837?term=NCT02605837&draw=2&rank=1 **4.** Data on file, Takeda Pharmaceuticals, Inc. **5.** Hudgens S, Evans C, Phillips E, et al. *J Patient Rep Outcomes.* 2017;1(1):3. **6.** Hirano I, Collins MH, Katzka DA, et al. *Clin Gastroenterol Hepatol.* 2022;20(3):525-534.e10. **7.** Dellon ES, Katzka DA, Collins MH, et al. *Gastroenterology.* 2017;152(4):776-786.e5. doi:10.1053/j.gastro.2016.11.021.

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