

*Relief is defined as a decrease in eosinophils (a type of white blood cell) in the esophagus and improvement in dysphagia (difficulty swallowing), as demonstrated by EOHILIA in two 12-week clinical trials.

What is EOHILIA?

EOHILIA (budesonide oral suspension) is a prescription oral corticosteroid medicine used for 12 weeks of treatment of Eosinophilic Esophagitis (EoE), in people 11 years and older.

EOHILIA has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

It is not known if EOHILIA is safe and effective in children under 11 years of age.

IMPORTANT SAFETY INFORMATION

Who should not take EOHILIA?

Do not take EOHILIA if you are allergic to budesonide.

Please see additional Important Safety Information throughout. Please see EOHILIA Prescribing Information and talk with your healthcare provider.



/hat is EoE?

EOHILIA Works

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Important Safety Information

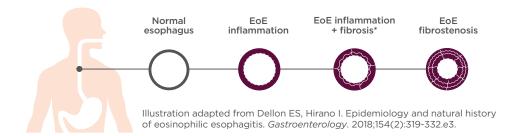


Safety Information

EoE explained

EoE is a chronic inflammatory disease that occurs in the esophagus—the tube that passes food and liquid from the throat down to the stomach. EoE causes inflammation in the esophagus, which can lead to it narrowing and symptoms like difficulty swallowing (dysphagia).

- EoE happens because the body's immune system may respond to certain allergens in the esophagus with a buildup of eosinophils (a type of white blood cell) and other inflammatory cells
- This buildup can result in inflammation that causes your EoE symptoms
- Left untreated, this inflammation may lead to physical damage to the esophagus, making symptoms worse

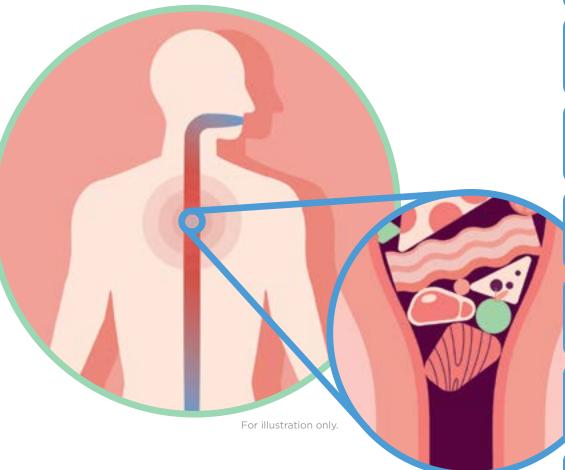


*Fibrosis is when inflammation leads to scarring, narrowing, and formation of excessive fibrous tissue in the lining of the esophagus.

EOE CAN BE DIFFICULT TO DIAGNOSE. FOR CHILDREN AND ADULTS, THE AVERAGE TIME TO DIAGNOSIS FROM THE FIRST SYMPTOM CAN BE ANYWHERE FROM 1 TO 8 YEARS, RESPECTIVELY.

Because of the nature of EoE, you may need to see certain specialists. These can include gastroenterologists, who specialize in treating conditions of the digestive system and can do tests, like an endoscopy, to more precisely diagnose EoE.

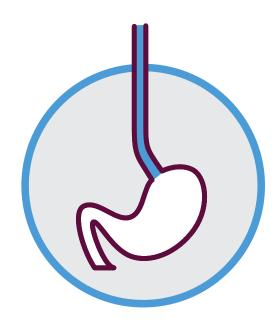
You may also need to see allergists and immunologists, who can test to see if you're allergic to certain foods and substances.



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What is EOHILIA?

EOHILIA is the **first and only 12-week oral, FDA-approved** treatment, designed to treat EoE patients 11 years and older.



EOHILIA helps to address inflammation in the esophagus

EOHILIA is a liquid-like form of budesonide (a corticosteroid) specifically designed to treat inflammation in the esophagus. While the exact way corticosteroids work on EoE inflammation is not known, EOHILIA works on a wide range of inflammatory cells.

IMPORTANT SAFETY INFORMATION (continued)

EOHILIA may cause serious side effects, including: (continued)

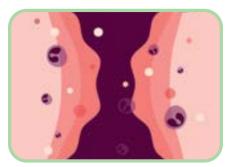
Adrenal suppression. Long-term use of EOHILIA can cause a condition in which the adrenal glands do not make enough steroid hormones (adrenal suppression). Tell your healthcare provider if you are under stress or if you have any of the following signs or symptoms:

- Tiredness
- Weakness
- Nausea and vomiting
- Low blood pressure

Please see additional Important Safety Information throughout. Please see EOHILIA Prescribing Information and talk with your healthcare provider.

EOHILIA is specifically formulated for the esophagus

For illustration only.



People with EoE have a high level of eosinophils (a type of white blood cell) and other inflammatory cells in their esophagus. When these build up, they can cause the symptoms of EoE.



Upon shaking, EOHILIA gets more fluid for swallowing, and then regains its original form.



EOHILIA is specifically designed to help reduce the eosinophils that contribute to inflammation in the esophagus in patients with EoE.



EOHILIA is the first and only 12-week oral, FDA-approved treatment for EoE.

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In a 12-week clinical study EOHILIA was

Proven effective for reducing inflammation in the esophagus and reducing difficulty swallowing

In a 12-week clinical study of 318 patients 11 years and older with EoE, 213 patients were treated with EOHILIA (2 mg twice daily), while 105 were given placebo.



Reduces difficulty swallowing

Patients taking EOHILIA had less difficulty swallowing.

Patients taking EOHILIA achieved a 10.2-point reduction in their overall Dysphagia Symptom Questionnaire (DSQ) score from when they started the study, while patients on placebo had a 6.5-point difference.*

The DSQ score was based on biweekly patient reports of their symptoms relating to difficulty swallowing. Scores ranged from 0-84, with higher scores indicating greater frequency and severity of dysphagia.



Reduces inflammation in the esophagus

More patients taking EOHILIA had a decrease in the number of eosinophils (a type of white blood cell that can contribute to EoE inflammation).

53% of patients taking EOHILIA had a decrease in the number of eosinophils compared to 1% of patients on placebo.[†]

*Patients experiencing less difficulty swallowing: Improvement in trouble swallowing with EOHILIA was calculated using the DSQ, a point-based self-assessment that patients took daily to track how frequently they experienced dysphagia symptoms and the severity of those symptoms while taking EOHILIA treatment. At the start of the study, the average biweekly DSQ score of patients taking EOHILIA was 30.3 and 30.4 for patients on placebo.

Patients with a reduction in eosinophils: 113 of 213 patients (53%) taking EOHILIA had a reduction in number of $eos in ophils \ vs\ 1\ of\ 105\ patients\ (1\%)\ receiving\ placebo\ after\ 12\ weeks.\ Reduction\ in\ eos in ophils\ with\ EOHILIA\ was$ calculated by counting the number of eosinophils under a microscope before and after treatment. Successful treatment response was defined as a reduction in the number of eosinophils in the esophagus to 6 or fewer per high-power field. The high-power field is the area of a slide visible under the high magnification system of a microscope.



These results were consistent in a second study

In a second, smaller study of 92 patients (50 on EOHILIA and 42 on placebo),

38% of EOHILIA patients had a reduction in eosinophils compared to 2.4% on placebo. EOHILIA patients had a 14.5 point reduction in the DSQ compared to 5.9 for placebo patients.

IMPORTANT SAFETY INFORMATION (continued)

EOHILIA may cause serious side effects, including: (continued)

Decreased ability of your body to fight infections (immunosuppression) and increased risk of infection.

Corticosteroid medicines, including EOHILIA, lower the ability of your immune system to fight infections and increase the risk of infections caused by viruses, bacteria, fungi, protozoans, or certain parasites. Corticosteroid medicines, including EOHILIA can also:

- Make current infections worse
- Increase the risk of infections spreading (disseminated)
- Increase the risk of making infections active again or making infections worse that have not been active (latent)
- Hide (mask) some signs of infection

Please see additional Important Safety Information throughout. Please see EOHILIA Prescribing Information and talk with your healthcare provider.

An established safety profile

The safety of EOHILIA was established in a 12-week clinical study of 213 adult and adolescent patients 11 years of age and older with EoE. Safety results were similar in a second, smaller study of 92 patients.

EOHILIA may cause serious side effects, including hypercorticism (effects of having too much corticosteroid medicine in your blood), adrenal suppression (a condition in which the adrenal glands do not make enough steroid hormones), immunosuppression (decreased ability of your body to fight infections) and increased risk of infection, erosive esophagitis (acid-related damage to the esophagus lining), effect on growth, worsening of allergies, and Kaposi's sarcoma.

In a 12-week clinical study, the most common side effects included:

Side effects	EOHILIA patients (n=213)	Placebo patients (n=105)
Respiratory tract infection	13%	11%
Fungal infections of the mouth, throat, and esophagus (thrush)	8%	2%
Headache	5%	2%
Infection of the stomach and intestine (gastroenteritis)	3%	1%
Sore throat	3%	2%
Adrenal suppression	2%	0%
Acid-related damage to the lining of the esophagus (erosive esophagitis)	2%	0%

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

Be sure to talk to your or your child's doctor about any side effects that are bothersome or do not go away.

Any time you're learning about a new medication, make sure to ask your doctor about potential side effects. It's an important part of the conversation. And it's important for you to understand both the benefits and the risks of treatment.

Please see additional Important Safety Information throughout. Please see EOHILIA Prescribing Information and talk with your healthcare provider.



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EOHILIA: Ready to use and fits into your daily routine



EOHILIA is a 12-week treatment that comes in conveniently packaged, premixed stick packs (oral administration, single-dose [2 mg/10 mL]). An easy schedule to remember and stick to is, "Once in the morning, Once in the evening."

The three-step overview for taking EOHILIA:

This is not all the information you need to know. Please refer to the <u>Instructions for Use</u> for complete information on how to take EOHILIA. Do not take with food or liquid.





1. Shake & snip: Shake the stick pack for at least 10 seconds before opening. Using scissors, cut along the dotted line straight across the top of the stick pack.



2. Squeeze & swallow: Take EOHILIA by squeezing the stick pack from the bottom to the top directly into the mouth. Repeat 2 to 3 times until all medicine is taken. Swallow all the EOHILIA suspension. Discard the empty stick pack in the household trash.



3. Spit & rinse: Do not eat or drink for 30 minutes after taking EOHILIA. After 30 minutes, rinse your mouth with water and spit out the contents without swallowing.

Do not mix EOHILIA with food or liquid. Avoid drinking grapefruit juice during treatment with EOHILIA. Do not eat or drink when taking EOHILIA and for at least 30 minutes after taking EOHILIA.

Please see additional Important Safety Information throughout. Please see EOHILIA Prescribing Information and talk with your healthcare provider.

EOHILIA is conveniently packaged

Treatment with EOHILIA provides consistent dosing every time you take it. The EOHILIA on-the-go stick packs do not need to be refrigerated. EOHILIA should be stored at controlled room temperatures between 36°F to 77°F. Do NOT freeze.

It's always ready to go.



Inspect package and DO NOT take if:

- Carton seal is broken
- The stick pack is damaged or leaking
- The expiration date has passed

IMPORTANT SAFETY INFORMATION (continued)

EOHILIA may cause serious side effects, including: (continued)

Decreased ability of your body to fight infections (immunosuppression) and increased risk of infection. (continued)

These infections can be mild but can be severe and lead to death. Your healthcare provider should check you closely for signs and symptoms of an infection while taking EOHILIA. Tell your healthcare provider right away about any signs or symptoms of a new or worsening infection while taking EOHILIA, including flu-like symptoms such as:

- Fever
- Chills
- Stomach area (abdominal) pain
- Aches
- Diarrhea

- Cough
- Pain
- Feeling tired
- Nausea and vomiting

What Is EoE?

EOHIL

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Taking

Need support?

Here's how the EOHILIA Patient Support and Copay Program works:

- **Sign up:** Eligible commercially insured patients may sign up for a digital copay card by visiting **EOHILIA.com/copay-savings/**, or calling **1-866-861-1482**. Signing up before going to the pharmacy may help with the insurance authorization process
- Save: Bring your digital copay card to the pharmacy to start on EOHILIA for as little as \$0*†

EOHILIA, like many other prescription medications, will likely need approval by your health insurance company for it to be covered. The doctor's office typically takes 1-2 weeks to complete this process.

Your Digital Copay Card Cutesome rediscoperation and Patients May Pay As Little As Powered by: Cuese Hauncane Bin PCN GRP (ID

Register for your copay card

If you register for the copay card, you'll be automatically enrolled for updates about EOHILIA delivered straight to your inbox.



Scan to sign up

*Eligible patients may pay as little as \$0 if EOHILIA (budesonide oral suspension) is covered by their commercial insurance, per 30-day supply of EOHILIA, with a max annual benefit of up to \$2500 off their copay or out-of-pocket expenses.

Please see Important Safety Information throughout. Please see EOHILIA <u>Prescribing Information</u> and talk with your healthcare provider.

Tips before heading to the pharmacy

Prescription savings: Find out if you are eligible for a copay card before going to the pharmacy. Be sure to give your pharmacist your copay card information before your prescription is run through insurance.

Filling your prescription: Your doctor will send an electronic prescription to your pharmacy to be filled. If you're given a paper prescription, you'll need to bring it to the pharmacy to be filled. Don't forget to bring your EOHILIA digital copay card.

Waiting on your prescription: Stay in touch with your doctor's office as they work through coverage for EOHILIA with your insurance company.

Other costs: Follow up with the pharmacy to discuss and consent to your out-of-pocket costs.

Picking up your prescription: Call your pharmacy to ensure they have your prescription ready and then pick it up no more than 1-2 days later.



[†]Please see Terms and Conditions on page 9.

EOHILIA™ (budesonide oral suspension) Copay Offer Terms and Conditions

Eligible patients may pay as little as \$0 if EOHILIA™ (budesonide oral suspension) is covered by their commercial insurance, up to \$600 per 30-day supply of EOHILIA™, with a max annual benefit of up to \$2500 off their copay or out-of-pocket expenses. A valid Prescriber ID# is required on the prescription. Offer not valid for cash paying patients. You must be 18 years or older to use the EOHILIA™ Copay Offer for yourself or a minor.

Patient Instructions: Follow the dosage instructions given by the doctor. This offer may not be redeemed for cash. By using this offer, you are certifying that you meet the eligibility criteria and will comply with the terms and conditions described in the Terms and Conditions section below and understand and acknowledge the Takeda Privacy Notice (www.takeda.com/privacy-notice). Patients with questions about the EOHILIA™ Copay Offer should call 1-866-861-1482.

Pharmacist Instructions: When you apply this offer, you certify that: (1) you have not submitted and will not submit a claim for reimbursement for the portion of the prescription covered by this offer to any payer; (2) your participation in this program is consistent with all applicable laws and any obligations, contractual or otherwise, that you may have as a pharmacy provider; (3) By participating in this program, you are certifying that you will comply with the terms and conditions described.

Pharmacist Instructions For A Patient With An Eligible Third Party: Submit the claim to the primary Third Party Payer first, then submit the balance due to CHANGE HEALTHCARE as a Secondary Payer COB [coordination of benefits] with patient responsibility amount and a valid Other Coverage Code, (e.g. 8). The patient pay amount submitted will be reduced by up to \$1800 and reimbursement will be received from CHANGE HEALTHCARE. Valid Other Coverage Code required. For any questions regarding Change Healthcare online processing, please call the Help Desk at 1-800-433-4893.

Terms and Conditions: The Eohilia™ Copay Offer ("Offer") provides financial support for commercially insured patients who qualify for the Offer. By using this Offer, the patient certifies that the program is intended solely for his or her benefit—not health plans and/or their partners. This Offer cannot be used if patient is a beneficiary of, or any part of the prescription is covered by: (1) any federal, state, or government-funded healthcare program (Medicare, Medicare Advantage, Medicaid, TRICARE, etc.), including a state pharmaceutical assistance program (the Federal Employees Health Benefit (FEHB) Program is not a government-funded healthcare program for the purpose of this Offer), (2) the Medicare Prescription Drug Program (Part D), or if patient is currently in the coverage gap, or (3) insurance that is paying the entire cost of the prescription. Patient may not seek reimbursement from any other plan or program (Flexible Spending Account [FSA], Health Savings Account [HSA], Health



Reimbursement Account [HRA], etc.) for any out-of-pocket costs covered by this Offer, Cash Discount Cards and other non-insurance plans are not valid as primary under this Offer. This does not constitute health insurance. By using this Offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this Offer. It is illegal to (or offer to) sell, purchase. or trade this Offer. This Offer is not transferable and is limited to one Offer per person and may not be combined with any other coupon, discount, prescription savings card, rebate, free trial, patient assistance, co-pay maximizer, alternative funding program, co-pay accumulator, or other offer, including those from third parties and companies that help insurers or health plan manage costs. This Offer is valid in the United States, including Puerto Rico and other U.S. territories. This Offer is not valid if reproduced. Void where prohibited by: your insurance provider, law, taxed, or restricted. By utilizing this Offer, you hereby accept and agree to abide by these terms and conditions. Any individual or entity who enrolls or assists in the enrollment of a patient in this Offer represents that the patient meets the eligibility criteria and other requirements described herein. You must meet the program eligibility requirements every time you use the program. Program managed by ConnectiveRx on behalf of Takeda Pharmaceuticals U.S.A., Inc. The parties reserve the right to rescind, revoke, or amend this Offer without notice at any time.

Please see Important Safety Information throughout. Please see EOHILIA <u>Prescribing Information</u> and talk with your healthcare provider.



Helpful diet tips

Here are some tips to help manage your EoE. Always be sure to talk to a doctor first about what's best—everyone's diet is different.

Avoid problem foods. Make a list of the foods you can't eat and keep it updated and with you at all times. Ask questions about ingredients when eating food other people prepare.

Focus on what you CAN eat. Use this as a chance to expand your palate by discovering new foods and ingredients that don't trigger your symptoms.

Always read food labels. Pay close attention to phrases like "may contain" to make sure food doesn't include ingredients you should be avoiding.

Plan and prep your meals. Create a menu for the week and, if you can, prep meals in advance to make sure you have all the necessary ingredients.

Allow extra time in the aisles. Grocery shopping may take longer than normal, so plan your trips so you don't feel rushed.

Learn how to cook with substitutions. A lot of recipes have ingredients that can be substituted, even for staples like wheat, milk, or eggs.

Speak to the manager. When eating at restaurants, explain your dietary restrictions to the manager. They're usually more than happy to help.

Plan for parties. When it comes to social gatherings involving food, consider eating at home beforehand or take your own safe dish (or two) to eat.



Please see additional Important Safety Information throughout. Please see EOHILIA <u>Prescribing Information</u> and talk with your healthcare provider.



IMPORTANT SAFETY INFORMATION

Who should not take EOHILIA?

Do not take EOHILIA if you are allergic to budesonide.

What are the possible side effects of EOHILIA? EOHILIA may cause serious side effects, including:

Effects of having too much corticosteroid medicine in your blood (hypercorticism).

Long-term use of EOHILIA may cause you to have elevated levels of corticosteroid medicine in your blood. Tell your healthcare provider if you have any of the following signs and symptoms:

- Acne
- Bruise easily
- Rounding of your face
- Ankle swelling
- Thicker body hair and facial hair
- A fatty pad or hump between your shoulders (buffalo hump)
- Pink or purple stretch marks on the skin of your abdomen, thighs, breasts, and arms

Adrenal suppression. Long-term use of EOHILIA can cause a condition in which the adrenal glands do not make enough steroid hormones (adrenal suppression). Tell your healthcare provider if you are under stress or if you have any of the following signs or symptoms:

- Tiredness
- Weakness
- Nausea and vomiting
- Low blood pressure

Decreased ability of your body to fight infections (immunosuppression) and increased risk of infection.

Corticosteroid medicines, including EOHILIA, lower the ability of your immune system to fight infections and increase the risk of infections caused by viruses, bacteria, fungi, protozoans, or certain parasites. Corticosteroid medicines, including EOHILIA can also:

- Make current infections worse
- Increase the risk of infections spreading (disseminated)
- Increase the risk of making infections active again or making infections worse that have not been active (latent)
- Hide (mask) some signs of infection

These infections can be mild but can be severe and lead to death. Your healthcare provider should check you closely for signs and symptoms of an infection while taking EOHILIA. Tell your healthcare provider right away about any signs or symptoms of a new or worsening infection while taking EOHILIA, including flu-like symptoms such as:

- Fever
- Chills
- Stomach area (abdominal) pain
- Aches
- Diarrhea
- Cough
- Pain
- Feeling tired
- Nausea and vomiting
- **Tuberculosis:** If you have inactive (latent) tuberculosis, your tuberculosis may become active again while taking EOHILIA. Your healthcare provider should check you closely for signs and symptoms of tuberculosis while taking EOHILIA.

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IMPORTANT SAFETY INFORMATION (continued)

Decreased ability of your body to fight infections (immunosuppression) and increased risk of infection. (continued)

- Chicken pox and measles: People taking corticosteroid medicines, including EOHILIA, who have not had chicken pox or measles, should avoid contact with people who have these diseases. Tell your healthcare provider right away if you come in contact with anyone who has chicken pox or measles.
- **Hepatitis B virus (HBV) reactivation:** If you are a carrier of HBV, the virus can become an active infection again while taking EOHILIA. Your healthcare provider will test you for HBV before you start taking EOHILIA.
- Amebiasis: Inactive (latent) amebiasis may become an active infection while taking EOHILIA. Your healthcare provider should check you for amebiasis before you start taking EOHILIA if you have spent time in the tropics or have unexplained diarrhea.
- Fungal infections of the mouth (thrush), throat, and esophagus in patients using EOHILIA may occur. Symptoms of infection include white spots in the mouth, a burning or painful sensation in your mouth, redness inside of your mouth, difficulty with eating or swallowing, loss of taste, and cotton feeling in your mouth. Tell your healthcare provider if any of the above symptoms occur.
- Erosive esophagitis. EOHILIA can cause acid-related damage to the lining of the esophagus. Tell your healthcare provider if you notice any new or worsening signs or symptoms: heartburn, chest pain, and trouble swallowing.
- Effect on growth. Taking corticosteroids can affect your child's growth. Tell your healthcare provider if you are worried about your child's growth. Your healthcare provider may monitor the growth of your child while taking EOHILIA.
- Worsening of allergies. If you take certain other corticosteroid medicines to treat
 allergies, switching to EOHILIA may cause your allergies to come back. These allergies
 may include a skin condition called eczema or inflammation inside your nose (rhinitis).
 Tell your healthcare provider if any of your allergies become worse while taking
 EOHILIA.
- Kaposi's sarcoma has happened in people who receive corticosteroid therapy, most often for treatment of long-lasting (chronic) conditions.

The most common side effects of EOHILIA include:

- Respiratory tract infection
- Fungal infections of the mouth, throat, and esophagus (thrush)
- Headache
- Infection of the stomach or intestine (gastroenteritis)
- Sore throat
- Adrenal suppression
- Acid-related damage to the lining of esophagus (erosive esophagitis)

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of EOHILIA. **You may report side effects to the FDA at 1-800-FDA-1088.**

What should I avoid while taking EOHILIA?

• Avoid drinking grapefruit juice while taking EOHILIA. Drinking grapefruit juice can increase the level of EOHILIA in your blood.

Before you take EOHILIA, tell your healthcare provider if you have any medical conditions, including if you have:

- Liver problems
- Are planning to have surgery
- Chicken pox, measles, or recently been near anyone with either
- Certain kinds of infection that have not been treated including:
 - Fungal infections
 - Bacterial infections
 - Viral infections
 - Parasitic infections, including threadworm (Strongyloides) infections.
 - Herpes simplex infection of the eye (ocular herpes simplex)

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IMPORTANT SAFETY INFORMATION (continued)

Before you take EOHILIA, tell your healthcare provider if you have any medical conditions, including if you have: (continued)

- Have or had tuberculosis
- Malaria of the brain (cerebral malaria)
- Infection of the mouth, throat, or esophagus
- Diabetes, glaucoma, or family history of either
- Cataracts
- High blood pressure (hypertension)
- Low bone mineral density or osteoporosis
- Stomach ulcers
- Are pregnant, plan to become pregnant, or think you may be pregnant. EOHILIA may harm your unborn baby. Talk to your healthcare provider about the possible risks.
- Are breastfeeding or plan to breastfeed. It is unknown if EOHILIA passes into your breast milk or affects your baby. Talk to your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What is EOHILIA?

EOHILIA (budesonide oral suspension) is a prescription oral corticosteroid medicine used for 12 weeks of treatment of Eosinophilic Esophagitis (EoE), in people 11 years and older.

EOHILIA has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks.

It is not known if EOHILIA is safe and effective in children under 11 years of age.

A 12-week oral, FDA-approved treatment proven to deliver EoE relief

Relief is defined as a decrease in eosinophils (a type of white blood cell) in the esophagus and improvement in dysphagia (difficulty swallowing) in two 12-week clinical trials.

- © EOHILIA is an oral treatment, <u>proven</u> effective for reducing both difficulty swallowing and inflammation in the esophagus
- EOHILIA is specifically formulated for the esophagus. While the exact way corticosteroids work on EoE inflammation is not known, EOHILIA works on a wide range of inflammatory cells
- EOHILIA has an established safety profile in clinical studies. The most common side effects included respiratory tract infection, fungal infections of the mouth, throat and esophagus (thrush), headache, infection of the stomach and intestine (gastroenteritis), sore throat, adrenal suppression, and acid-related damage to the esophagus (erosive esophagitis)







Takeda