

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.



Welcome!

You've taken the first step in starting treatment with EOHILIA. The sooner you start treatment, the sooner you may see improvement in your eosinophilic esophagitis (EoE) symptoms.

How does EOHILIA work?

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.







Illustration of esophagus.

EOHILIA is premixed in convenient, on-the-go stick packs that do not need to be refrigerated. Upon shaking the stick pack, EOHILIA gets more fluid for swallowing and then regains its original form.

What to expect when you take EOHILIA:



It's important to complete the full course of treatment and take the medicine exactly as prescribed by your doctor to best support your experience.



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."



If you have any concerns throughout your treatment journey, **talk to your doctor**.

IMPORTANT SAFETY INFORMATION

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

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

Things to remember as you take EOHILIA:

This is not all of the important information you need to know before taking EOHILIA.

Please refer to the <u>Instructions for Use</u>.



Do not mix EOHILIA with food or liquid.

Just take it exactly as prescribed from the convenient, single-dose stick pack.



Do not take EOHILIA with food or liquid. Do not eat or drink for 30 minutes after taking EOHILIA.



Avoid drinking grapefruit juice during treatment with

EOHILIA; this can increase the level of EOHILIA in your blood.



Stick pack in hand? Let's get started.

This is not all of the important information you need to know before taking EOHILIA. Please refer to the <u>Instructions for Use</u>.

The three-step overview for taking EOHILIA:

Do not take with food or liquid.



1. Shake & snip: Shake the stick pack well 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 given. Swallow all the EOHILIA suspension. Discard the empty stick pack in the household trash.



3. Rinse & spit: 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 change your dose or stop taking EOHILIA unless your healthcare provider tells you.

IMPORTANT SAFETY INFORMATION

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

The EOHILIA Patient Support and Copay Program is here for you

The EOHILIA Patient Support and Copay Program is designed to help guide you along your EOHILIA treatment journey. For those with commercial insurance, you may be eligible to pay as little as \$0* for EOHILIA.



Waiting on your prescription?

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.

Stay in touch with your doctor's office or pharmacist while they work through insurance coverage for EOHILIA.

*Please see Terms and Conditions on reverse side.

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



There are 2 ways to register:

- Online at EOHILIA.com/copay-savings/
- By calling **1-866-861-1482**



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.

IMPORTANT SAFETY INFORMATION FOR EOHILIA™ (budesonide oral suspension)

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.



IMPORTANT SAFETY INFORMATION FOR EOHILIATM (budesonide oral suspension) (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)
- 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.

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

