

## **PATIENT INFORMATION**

### **EOHILIA™ (ee-oh-HIL-ee-uh) (budesonide oral suspension)**

#### **What is EOHILIA?**

EOHILIA 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 younger than 11 years of age.

#### **Who should not take EOHILIA?**

##### **Do not take EOHILIA if:**

- you are allergic to budesonide.

#### **Before you take EOHILIA tell your healthcare provider if you have any other medical conditions including if you:**

- have liver problems.
- are planning to have surgery.
- have chicken pox or measles or have recently been near anyone with chicken pox or measles.
- have 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.
- have malaria of the brain (cerebral malaria).
- have an infection of the mouth, throat, or esophagus.
- have diabetes or glaucoma or have a family history of diabetes or glaucoma.
- have cataracts.
- have high blood pressure (hypertension).
- have low bone mineral density or osteoporosis.
- have stomach ulcers.
- are pregnant or plan to become pregnant. EOHILIA may harm your unborn baby. Talk to your healthcare provider about the possible risk to your unborn baby if you take EOHILIA when you are pregnant. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during your treatment with EOHILIA.
- are breastfeeding or plan to breastfeed. It is not known if EOHILIA passes into your breast milk or if it will affect your baby. Talk to your healthcare provider about the best way to feed your baby if you take EOHILIA.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the counter medicines, vitamins, and herbal supplements. EOHILIA and other medicines may affect each other causing side effects.

#### **How should I take EOHILIA?**

- **See the detailed Instructions for Use that comes with EOHILIA for information about how to prepare and take EOHILIA and how to properly store and throw away (dispose of) used EOHILIA stick packs.**
- Take EOHILIA exactly as your healthcare provider tells you. Your healthcare provider will tell you how much EOHILIA to take.
- EOHILIA is taken by mouth, 2 times a day (1 time in the morning and 1 time in the evening).
- Do not mix EOHILIA with food or liquid.
- **Do not eat or drink at the same time as taking EOHILIA. Wait to eat or drink at least 30 minutes after taking EOHILIA.**
- Your healthcare provider may change your dose if needed. **Do not change your dose or stop taking EOHILIA unless your healthcare provider tells you.**

#### **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.

## 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.
- 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
  - 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:** 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 and intestine (gastroenteritis)
- sore throat
- adrenal suppression
- acid-related damage to the lining of the 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. For more information, ask your healthcare provider or pharmacist.

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

**How should I store EOHILIA?**

Store between 36°F to 77°F (2°C to 25°C). May be refrigerated. **Do not freeze.**

**Keep EOHILIA and all medicines out of the reach of children.**

**General information about the safe and effective use of EOHILIA.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use EOHILIA for a condition for which it was not prescribed.

Do not give EOHILIA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about EOHILIA that is written for health professionals.

**What are the ingredients in EOHILIA?**

**Active ingredient:** budesonide

**Inactive ingredients:** acesulfame potassium, ascorbic acid, Avicel® RC-591, cherry flavor, citric acid, dextrose, disodium ethylenediaminetetraacetic acid (EDTA), glycerin, Magnasweet® 110, maltodextrin, polysorbate 80, potassium sorbate, sodium ascorbate, sodium benzoate, sodium citrate, and purified water. Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye).

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For more information, go to [www.EOHILIA.com](http://www.EOHILIA.com) or call 1-877-TAKEDA-7 (1-877-825-3327).

**INSTRUCTIONS FOR USE**  
**EOHILIA™ (ee-oh-HIL-ee-uh)**  
**(budesonide)**  
**suspension, for oral use**

This Instructions for Use contains information on how to take EOHILIA.

**Important Information You Need to Know Before Taking EOHILIA**

**For oral use only** (take by mouth).

Take EOHILIA exactly as your healthcare provider tells you. Your healthcare provider will tell you how much EOHILIA to take.

- **EOHILIA is taken by mouth, 2 times a day (1 time in the morning and 1 time in the evening).**
- **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.**
- Your healthcare provider may change your dose if needed. **Do not change your dose or stop taking EOHILIA unless your healthcare provider tells you.**





**EOHILIA is provided as a single-dose 10 mL stick pack intended for oral use.**

**Inspect package and do not take if:**

- carton seal is broken or
- the stick pack is damaged or leaking.
- the expiration date (EXP) has passed.

**Taking EOHILIA**

**How to take EOHILIA STICK PACK:**

|               |  |  |
|---------------|--|--|
| <b>Step 1</b> | <br><b>Figure A</b>   | <ul style="list-style-type: none"><li>• <b>Do not</b> take EOHILIA with food or liquid (see Figure A).</li></ul>   |
| <b>Step 2</b> | <br><b>Figure B</b> | <ul style="list-style-type: none"><li>• Shake the stick pack well for at least 10 seconds before opening (see Figure B).</li><li>• Using scissors, cut along the dotted line straight across the top of the stick pack.</li></ul>  |
| <b>Step 3</b> | <br><b>Figure C</b> | <ul style="list-style-type: none"><li>• Take EOHILIA by squeezing the stick pack from the bottom to the top directly into the mouth (see Figure C).</li><li>• Repeat 2 to 3 times until all the medicine is given.</li><li>• Swallow all the EOHILIA suspension.</li><li>• Throw away (discard) the empty stick pack in the household trash.</li></ul> |
| <b>Step 4</b> | <br><b>Figure D</b> | <ul style="list-style-type: none"><li>• Do not eat or drink for 30 minutes after taking EOHILIA (see Figure D).</li><li>• After 30 minutes, rinse your mouth with water and spit out the contents without swallowing.</li></ul>  |

**Storing EOHILIA**

Store refrigerated or at controlled room temperature at 36°F to 77°F (2°C to 25°C). Excursions up to 86°F (30°C) are acceptable.

**Do not freeze.**

**Keep EOHILIA and all medicines out of the reach of children.**

**Disposing of EOHILIA**

Throw away (discard) the empty EOHILIA stick pack in the household trash.

For more information, go to [www.EOHILIA.com](http://www.EOHILIA.com) or call 1-877-TAKEDA-7 (1-877-825-3327).

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