Ekterly®
(sebetralstat) tablets 300 mg

Meet Zach,
a real EKTERLY patient

Age 24 | HAE Type II

Zach is an outgoing and lifelong adventurer who refuses to let hereditary angioedema (HAE) hold him back. From **early life-threatening laryngeal attacks to the clinical trial for EKTERLY® (sebetralstat)**, Zach's journey reflects the power of treating early and finding confidence in an on-demand treatment that works for him.

INDICATION

EKTERLY® (sebetralstat) is a plasma kallikrein inhibitor indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older.

IMPORTANT SAFETY INFORMATION

Adverse reactions: The most commonly reported adverse reaction was headache.

Please see additional Important Safety Information throughout.
Please see full Prescribing Information.

Medical history

DIAGNOSIS:

Type II HAE, 18 months old

FAMILY HISTORY:

Father, brother, sister (HAE)

CURRENT HAE TREATMENT:

- **Prophylactic:** Subcutaneous preventive therapy
- **On-demand:** EKTERLY[1]

Zach's HAE attack profile

Here are the key details of Zach's attacks:

Triggers

- Physical exertion
- Stress
- Travel fatigue
- Injury or illness

Symptoms

- Laryngeal swelling (first major laryngeal attack at age 13-14)
- Abdominal pain and vomiting
- Facial, hand, and foot swelling

Frequency

- Before prophylaxis: severe attacks twice a month lasting 2-3 days
- After prophylaxis: reduced number of attacks but breakthrough attacks occur in hands, feet, and stomach

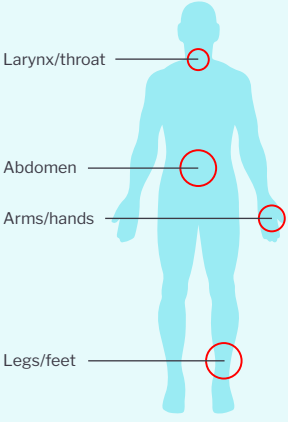
Attack management

- Treats every recognized attack within the first hour

Attack locations

Since childhood, Zach's attacks have occurred across multiple regions of his body—most notably his throat, extremities, and abdomen.

Attack sites treated with EKTERLY



"When I was 13, I had a laryngeal attack that nearly cost me my life. We were 6 hours from the nearest hospital that could help."

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With EKTERLY, patients like Zach can treat attacks without delay[2]

KONFIDENT TRIAL PRIMARY ENDPOINT*:

Median time to the beginning of symptom relief[1,2]

Based on prespecifying that attacks with incomplete data were censored at timepoint zero. Analysis included in label assigns these attacks a value of 12 hours, resulting in a median of 2.0 hours.[1,2]

Results seen with laryngeal and abdominal attacks were consistent with those observed across all attacks in both KONFIDENT and KONFIDENT-S[2,3,†]

1.3 hours median time to the beginning of symptom relief for **laryngeal and abdominal attacks**, with no reports of difficulty swallowing EKTERLY[3,‡,§,¶]

32 laryngeal attacks and **533** abdominal attacks were treated regardless of severity[3]

In KONFIDENT, safety events with EKTERLY were similar to placebo and consistent with the ongoing KONFIDENT-S trial.[1,4]

- **0 discontinuations due to adverse events**[2]

*KONFIDENT was a multinational, randomized, double-blind, placebo-controlled, phase 3, crossover study of 136 patients from 17 countries. Study participants were randomized to receive either placebo, EKTERLY 300 mg, or EKTERLY 600 mg to treat 3 attacks in a 3-way crossover design using 1 of 6 treatment sequences.[2,5]

†KONFIDENT-S is a multicenter, open-label extension trial of adult and adolescent patients (≥12 years of age; [N=134]). Study participants had a confirmed diagnosis of HAE and ≥2 attacks within 3 months and were enrolled after completing the KONFIDENT phase 3 trial or de novo.[3]

‡Data cutoff September 14, 2024.[3]

§Patients with laryngeal attacks were instructed to treat immediately with conventional on-demand treatment if laryngeal attack symptoms worsened after initial treatment with EKTERLY.[6]

¶Analysis allowed missing values between consecutive timepoints.[3]

IMPORTANT SAFETY INFORMATION

Drug interactions: EKTERLY is a substrate of CYP3A4. Concomitant use of EKTERLY with a strong CYP3A4 inhibitor increases sebetralstat exposure, which may increase the risk of sebetralstat adverse reactions.

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Use in specific populations: Avoid use of EKTERLY in patients with severe hepatic impairment (Child-Pugh Class C). The recommended dosage of EKTERLY is one dose of 300 mg (one tablet) in patients with moderate hepatic impairment (Child-Pugh Class B).

There are no available data on EKTERLY in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are no data on the presence of sebetralstat or its metabolite in human milk, the effects on the breastfed infant, or the effects on milk production.

The safety and effectiveness of EKTERLY in pediatric patients aged under 12 years of age have not been established.

To report SUSPECTED ADVERSE REACTIONS, contact KalVista Pharmaceuticals, Inc. at **1-855-258-4782** or FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Please see full accompanying **Prescribing Information**.

References: 1. EKTERLY. Package insert. KalVista Pharmaceuticals, Inc.; 2025. **2.** Riedl MA, Farkas H, Aygören-Pürsün E, et al. Oral sebetralstat for on-demand treatment of hereditary angioedema attacks. *N Engl J Med.* 2024;391(1):32-43. doi:10.1056/ NEJMoa2314192 **3.** Bernstein JA, Aygören-Pürsün E, Cancian M, et al. Sebetralstat for on-demand treatment of mucosal hereditary angioedema attacks in KONFIDENT-S. *Clin Transl Allergy*. 2025;15(11):e70118. doi: 10.1002/clt2.70118 **4.** Farkas H, Anderson J, Bouillet L, et al. Long-term safety and effectiveness of sebetralstat: interim analysis of KONFIDENT-S open-label extension. *J Allergy Clin Immunol Pract.* 2025;13(11):3094-3103.e5. doi:10.1016/j.jaip.2025.08.020 **5.** Riedl MA, Farkas H, Aygören-Pürsün E, et al. Oral sebetralstat for on-demand treatment of hereditary angioedema attacks. *N Engl J Med.* 2024;391(1)(suppl 1):1-33. doi:10.1056/NEJMoa2314192 **6.** Data on File. KalVista Pharmaceuticals, Inc. 2024.

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