

The logo for Ekterly, featuring the word "Ekterly" in a blue sans-serif font with a stylized orange and yellow swoosh under the "E".

(sebetralstat) tablets 300 mg

Meet Mistie, a real EKTERLY patient

Age 41 | HAE with normal C1 inhibitor

After years of unexplained symptoms, misdiagnoses, and severe attacks, Mistie finally received a diagnosis of hereditary angioedema (HAE) with normal C1 inhibitor in 2018. Her journey reflects the challenges many patients face in reaching an HAE diagnosis and the importance of having an on-demand treatment option available at the first sign of an attack.



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 (3.2%).

**Please see additional Important Safety Information throughout.
Please see full [Prescribing Information](#).**

Medical history

DIAGNOSIS:

HAE with normal C1 inhibitor, diagnosed in 2018

CURRENT HAE TREATMENT:

- **Prophylactic:** Injections
- **On-demand:** EKTERLY¹

FAMILY HISTORY:

Daughters (HAE)



Mistie's HAE attack profile

Here are the key details of Mistie's attacks:

Triggers

- Dietary factors
- Physical pressure (eg, clothing seams)
- Surgeries
- Stress
- Weather (eg, barometric changes)
- Hormonal events

Symptoms

- Massive headaches
- Swelling in abdomen, face, throat, and extremities
- Pain in abdomen
- Skin welts and numbness
- Airway compromised from severe attacks

Frequency

- Before diagnosis: A severe uncontrolled phase with multiple attacks per week, occasionally overlapping
- Multiple times a week

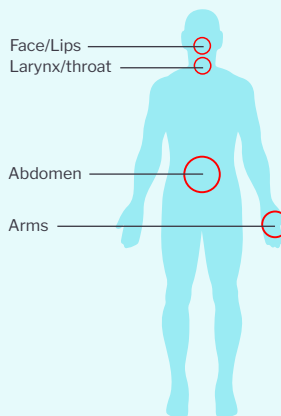
Attack management

- Limited access previously led to difficult decisions on which attacks to treat
- Now treats at first sign of symptoms

Attack locations

Mistie's attacks have occurred across almost all her body—including her abdomen, face, lips, throat, hands, arms, extremities, and chest—with symptoms progressing over time from isolated abdominal episodes to widespread and sometimes severe swelling.

Attack sites treated with EKTERLY



“For me, EKTERLY has given me back parts of myself I didn't know I had lost.”

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With EKTERLY, patients like Mistie can treat attacks without delay²

KONFIDENT TRIAL PRIMARY ENDPOINT*:

Median time to the beginning of symptom relief^{†,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 abdominal and laryngeal 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 **abdominal and laryngeal attacks**, with no reports of difficulty swallowing EKTERLY^{3,†§¶}

533 abdominal attacks and **32** laryngeal attacks were treated regardless of severity³

In KONFIDENT, safety events with EKTERLY were similar to placebo and consistent with the ongoing KONFIDENT-S trial. The most commonly reported adverse event in KONFIDENT was headache (3.2%). In KONFIDENT-S, the most commonly reported adverse events were headache (3.7%) and vomiting (2.2%).^{1,4,5}

- 0 discontinuations due to adverse events²

*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.^{2,6}

†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.⁷

¶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 [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/ctt2.70118 **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.** Data on File. KalVista Pharmaceuticals, Inc. 2024. **6.** 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 **7.** Data on File. KalVista Pharmaceuticals, Inc. 2024.