

Ekterly[®]
(sebetralstat) tablets 300 mg

Meet Ellis & Hortencia, A real EKTERLY patient and his caregiver

Age 14 | HAE Type 1

Ellis, a 14-year-old living with hereditary angioedema (HAE), experienced years of recurrent attacks before receiving a diagnosis. Guided by his mother **Hortencia's advocacy and vigilance**, their journey reflects the **essential role caregivers play** in early recognition, care navigation, and ensuring timely access to on-demand treatment.

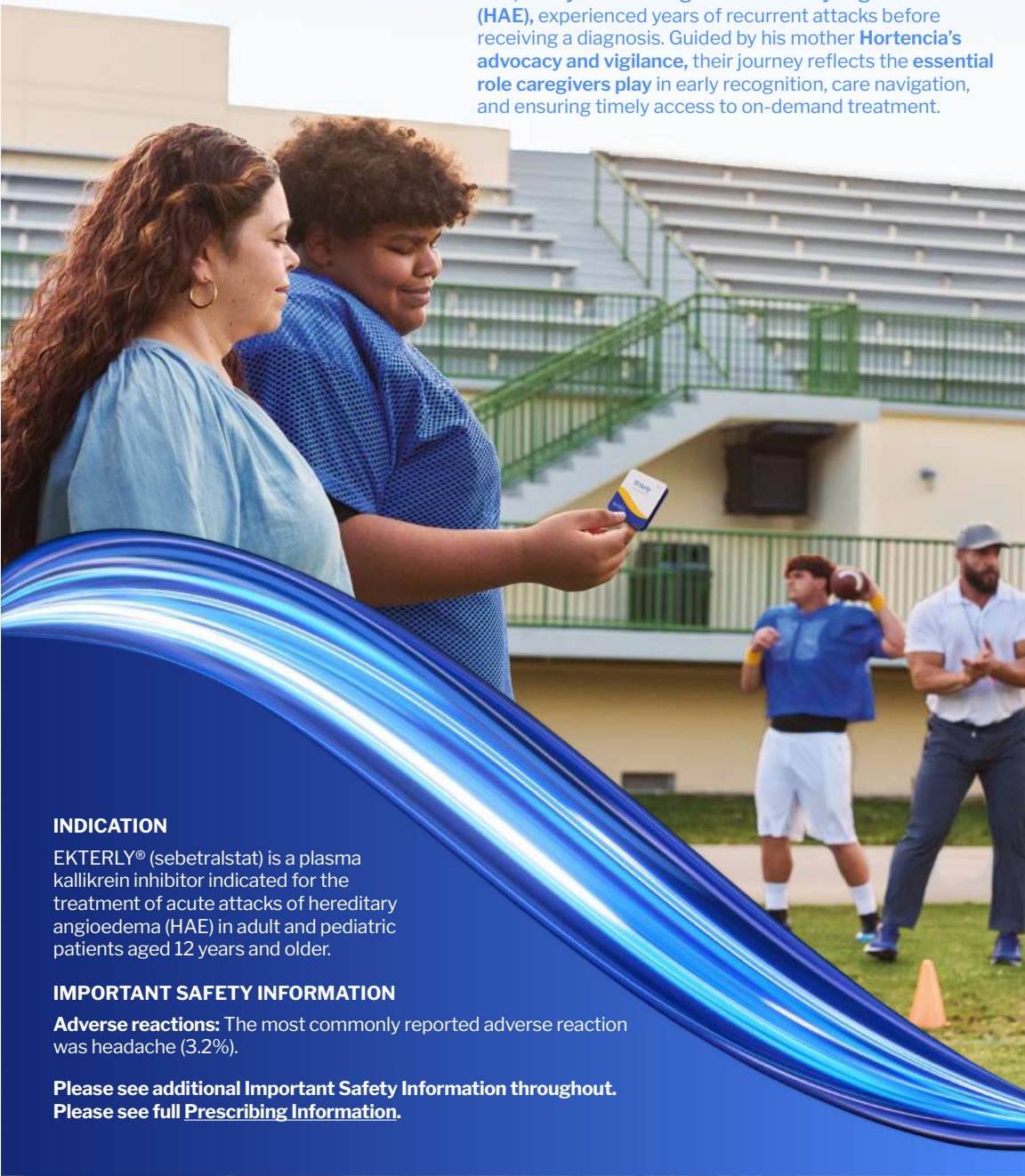
INDICATION

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:

Type 1 HAE, 12 years old (2024)

FAMILY HISTORY:

HAE on father's side

CURRENT HAE TREATMENT:

- **Prophylactic:** Injection administered 2x per month
- **On-demand:** EKTERLY¹



Ellis's HAE Attack Profile

Here are the key details of Ellis's attacks:

Triggers

- Seemingly anything can trigger attacks, including anxiety, stress, weather, and illness
- Sometimes, no recognized trigger can be found

Symptoms

- Fatigue
- Occasional rash
- Swelling
- Abdominal pain

Frequency

- Currently down to 1-2 attacks per week

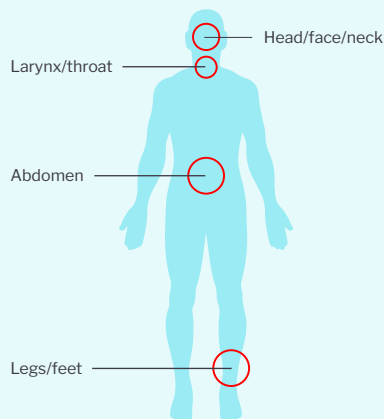
Attack management

- Treat at the start of attacks, then 3 hours later if needed
- Abdominal attacks are treated with additional medications and fluids

Attack locations

Over time, Hortencia became attuned to Ellis's early warning signs—such as abdominal discomfort and facial swelling—to support prompt treatment at symptom onset. Ellis's attacks have involved multiple regions, most notably the abdomen, face, and throat.

Attack sites treated with EKTERLY



“ Introducing an effective on-demand medication that works for Ellis has given us time—time we often lost sitting in ERs.

—Hortencia, Ellis's mother and caregiver

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EKTERLY is the **first and only oral treatment** that lets patients like Ellis treat at attack recognition^{1,2}

At practice, in school, or at home, patients can treat¹



ANYTIME

No preparation or setup required¹



ANYWHERE

Easily stored in a pocket, wallet, or backpack¹

Among adolescents, EKTERLY enables rapid time to treatment and beginning of symptom relief^{3,*}

Median time to treatment
from attack onset
(369 attacks)

9.0
minutes

Median time to the beginning
of symptom relief[†]
(369 attacks)

1.8
hours



94% of attacks that achieved beginning of symptom relief did so with only one dose^{3,‡}

The safety of EKTERLY in adolescents was consistent with study results for adult patients¹

No adolescent patients discontinued treatment due to AEs³

*EKTERLY was evaluated in the KONFIDENT trial and the KONFIDENT-S ongoing 2-year, open-label extension. Analysis in the adolescent population is from KONFIDENT-S (ages 12-17 years; n=23).^{1,4}

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. The primary endpoint was time to the beginning of symptom relief according to the 7-point Patient Global Impression of Change scale.^{5,6}

KONFIDENT-S is a multicenter, open-label extension trial of 134 adult and adolescent (≥12 years of age) patients. 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. Data cutoff date of September 14, 2024. Analysis included 1706 attacks treated with EKTERLY 600 mg.^{4,7}

[†]This analysis allowed missing values between 2 timepoints that achieved the endpoint.³

[‡]Among 255 of a total of 369 (69.1%) attacks achieved the beginning of symptom relief within 12 hours.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.** KalVista Pharmaceuticals announces FDA approval of EKTERLY (sebetralstat), first and only oral on demand treatment for hereditary angioedema. Published July 2025. Accessed July 2025. **3.** Data on File. KalVista Pharmaceuticals, Inc. 2024. **4.** Data on File. KalVista Pharmaceuticals, Inc. 2024. **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):32-43. doi:10.1056/NEJMoa2314192 **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.