

Less is more.

Hereditary angioedema (HAE)

attack prevention doesn't need to be complicated.

ORLADEYO® offers significant attack rate reduction, a convenient daily capsule, and long-term safety data.^{1,2}

Capsule not actual size

INDICATION

ORLADEYO® (berotralstat) is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

Limitations of use

The safety and effectiveness of ORLADEYO for the treatment of acute HAE attacks have not been established. ORLADEYO should not be used for the treatment of acute HAE attacks. Additional doses or dosages of ORLADEYO higher than 150 mg once daily are not recommended due to the potential for QT prolongation.

Please see Important Safety Information on page 13 and accompanying full Prescribing Information.

orladeyo®
(berotralstat) capsules 150 mg



Patients with HAE are likely struggling with disease and treatment burden^{3,4}

Self-administration challenges, needle fatigue, and other issues may be weighing patients down³

In a study of 75 adults living with HAE, approximately 90% of patients say they have learned to **tolerate** difficult aspects of their treatment, while 75% of patients say they **try not to think about** the demanding nature of their treatment.³

With the treatment landscape changing, you can talk with your patients about their satisfaction with their current therapy and what approach might best meet their needs.

Prophylactic therapy should be determined based on individual considerations^{4,5}:



Disease-related factors (physical, emotional, quality of life)



Treatment-related factors (route of administration, side effects, availability/supply)



Patient preference (lifestyle, dosing schedule, flexibility)

Research shows there is a strong patient demand for an oral prophylactic therapy⁶

Data from a study of 75 patients with HAE demonstrate the preference for an oral preventative therapy.⁶



of the 48 patients on a prophylactic therapy would **prefer an oral treatment** if one were available even though they are satisfied with their current prophylactic therapy⁶



of the 48 patients on a prophylactic therapy agree that an **oral prophylactic therapy would better fit their lives** vs an injectable HAE medication⁶

Shared decision making empowers patients to play a more active role in treatment decisions and be more compliant with their treatment, leading to better overall outcomes.⁷

ORLADEYO[®] is the first and only targeted oral prophylactic therapy for HAE¹

ORLADEYO offers the convenient oral administration your patients have hoped for^{1,6}

As a single 150 mg^a capsule taken once daily with food, ORLADEYO provides simple and straightforward dosing and administration without the need for cumbersome supplies and storage.¹



Oral administration

No need for injection, infusion, or related supplies¹



Flexibility

May be taken anywhere and at any time, at the same time each day, with food^{1,8}



Easy storage

Room temperature; no refrigeration required¹

ORLADEYO offers the consistency of daily dosing with the simplicity of oral administration.^{1,a}

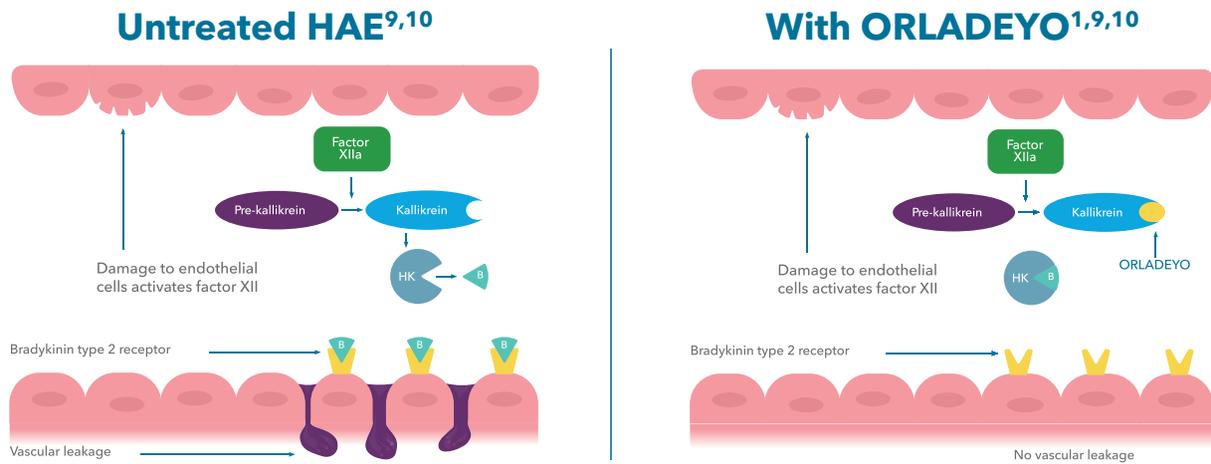
^aA reduced dosage of 110 mg taken orally once daily with food is recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) and in patients taking chronically administered P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (eg, cyclosporine).¹

SELECT IMPORTANT SAFETY INFORMATION

An increase in QT prolongation was observed at dosages higher than the recommended 150 mg once-daily dosage and was concentration dependent.

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ORLADEYO[®]: a daily capsule that targets and inhibits plasma kallikrein¹



In HAE, uncontrolled plasma kallikrein activity triggers an overproduction of bradykinin, which leads to vasodilation, vascular leakage, and subsequent swelling.

By decreasing plasma kallikrein activity, ORLADEYO prevents the cleavage of HK and subsequent release of bradykinin, ultimately preventing HAE attacks.

Abbreviations: B, bradykinin; factor XIIa, activated factor XII; HK, high-molecular-weight kininogen.

ORLADEYO was studied in one of the largest clinical studies for a prophylactic therapy in HAE^{1,11}

APeX-2 is a 3-part, double-blind, placebo-controlled study¹

Participants¹¹	121 patients (≥12 years of age) with confirmed HAE type 1 or 2 who experienced ≥2 investigator-confirmed attacks during the 8-week run-in period ^a		
Length of study^{2,11,12}	Part 1 (randomized 1:1:1)	Part 2 (dose blinded) ^b	Part 3 (open label)
	24 weeks (day 1-week 24)	24 weeks (week 24-48)	48 weeks (week 48-96)
Daily dosing regimen^{2,11,12}	Berotralstat 150 mg, berotralstat 110 mg, or placebo	Berotralstat 150 mg or berotralstat 110 mg	Berotralstat 150 mg

^aPatients were allowed to use rescue medications to treat attacks but had to discontinue all prophylactic HAE medications prior to the start of the study.¹¹

^bIn part 2 of the study, patients on active drug in part 1 continued on the same dose and patients on placebo in part 1 were rerandomized to a blinded active dose.¹²

SELECT IMPORTANT SAFETY INFORMATION

The most common adverse reactions (≥10% and higher than placebo) in patients receiving ORLADEYO were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.

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Patients in APeX-2 had considerable disease burden and a history of past prophylactic treatment use⁸

Demographics and baseline characteristics of intent-to-treat population (N=121) ⁸	
Median age (min, max)	40 (12, 74)
Female, n (%)	80 (66%)
Median baseline investigator-confirmed attack rate, attacks/month (range) ^a	2.90 (0.86-6.67)
Baseline attack rate of ≥ 2 attacks per month, n (%) ^b	85 (70%)
Median age at symptom onset (min, max)	11 (0.5, 55.0)
History of laryngeal attack, n (%)	90 (74%)
Use of past prophylactic treatment for HAE, n (%) ^c	91 (75%)
Any past prophylactic C1 esterase inhibitor (C1-INH) use, n (%) ^d	53 (44%)
Any past prophylactic androgen use, n (%) ^e	65 (54%)

^aBaseline investigator-confirmed attack rate was defined as (total number of investigator-confirmed HAE attacks experienced in the period between screening and first date/time of study drug) x 28/(date of first dose - date of screening + 1).⁸

^bBased on 120 subjects. One subject was randomized but did not receive study drug. As this subject did not receive drug, the subject had no baseline calculations.⁸

^cResponses for individual drugs may not be mutually exclusive. Percentages were based on the number of responses per category and may not sum to 100%.⁸

^dIncludes plasma-derived C1-INH replacement, recombinant C1-INH replacement, and fresh frozen plasma.⁸

^eIncludes unspecified androgens, oxandrolone, methyl-testosterone, danazol, and stanozolol.⁸

SELECT IMPORTANT SAFETY INFORMATION

A reduced dosage of 110 mg taken orally once daily with food is recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) and in patients taking chronically administered P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (eg, cyclosporine).

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ORLADEYO[®] offers significant attack rate reduction¹

APeX-2 part 1 primary efficacy endpoint: HAE attack rate over 24 weeks^{1,11}

- ORLADEYO demonstrated a significant attack rate reduction over 24 weeks^{1,11,a}
 - Patients receiving ORLADEYO saw a reduction from 3.06 to 1.31 attacks per month
 - Patients receiving placebo saw a reduction from 2.91 to 2.35 attacks per month
 - ORLADEYO demonstrated a 44% reduction vs placebo ($P < 0.001$)
- The effect of ORLADEYO in reducing attacks was seen within the first 4 weeks and maintained over 24 weeks¹

^aThe percent reduction in attack rate was greater with ORLADEYO 150 mg relative to placebo regardless of attack rate during the run-in period.¹

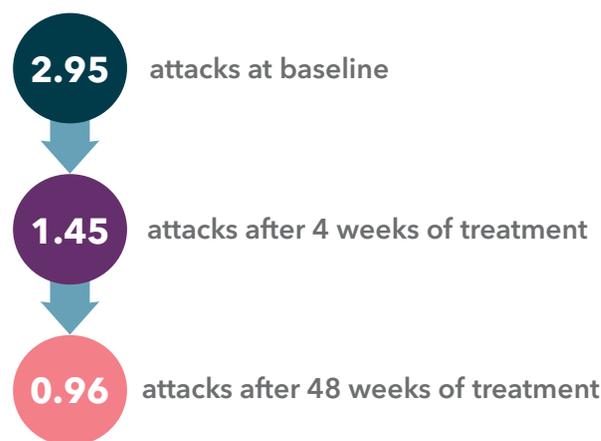
ORLADEYO reduced the need for rescue therapy¹¹

In an ad hoc analysis of the first 24 weeks of treatment, patients treated with ORLADEYO 150 mg experienced a reduction in rescue medication use per 28 days vs placebo (nominal $P < 0.001$).¹¹



Results with ORLADEYO seen in APeX-2 part 1 continued into part 2^{8,12}

Of the 31 patients who were randomized to ORLADEYO 150 mg at the beginning of APeX-2 and completed 48 weeks of treatment, the mean attack rate per 4 weeks declined from baseline to 48 weeks of treatment with ORLADEYO^{8,12}:



Every individual with HAE responds differently to treatment. The clinical phenotype is variable and does not predict response to prophylactic therapy.^{4,5}

SELECT IMPORTANT SAFETY INFORMATION

Berotrastat is a substrate of P-gp and BCRP. P-gp inducers (eg, rifampin, St. John's wort) may decrease berotrastat plasma concentration, leading to reduced efficacy of ORLADEYO. The use of P-gp inducers is not recommended with ORLADEYO.

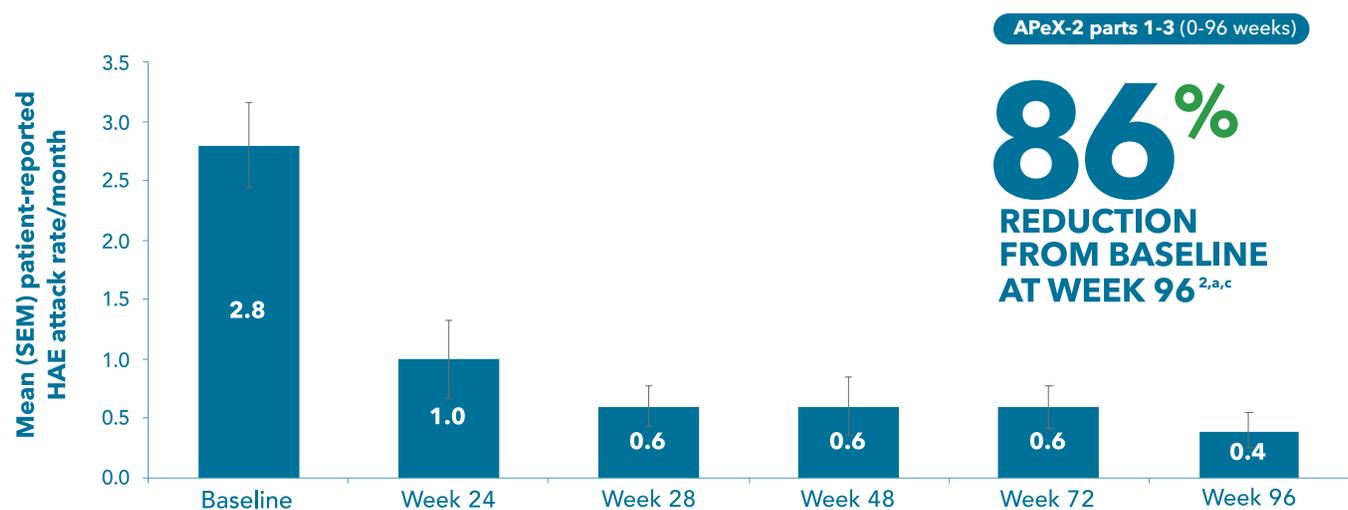
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ORLADEYO[®] provides sustained HAE attack rate reduction²

HAE attack rate reductions were seen within 4 weeks of starting ORLADEYO and were maintained over 96 weeks^{1,2}

- Twenty-one patients who were randomized to ORLADEYO 150 mg at the beginning of APeX-2 and completed 96 weeks of treatment demonstrated a decline in mean attack rate per 4 weeks from baseline to 96 weeks of treatment^{2,a}

HAE attack rate^b per month²



Abbreviation: SEM, standard error of the mean.

^aThis reflects an ad hoc analysis of interim data.⁸

^bDue to study design, investigator-confirmed attack rates were reported only during the first 48 weeks, while patient-reported attack rates were reported during weeks 49 to 96. For consistency across the entire 96 weeks, only patient-reported attack rates are reported. For analysis purposes, 1 month was defined as 4 weeks of treatment.²

^c86% attack rate reduction from baseline to week 96 was seen for patients who completed 96 weeks of treatment with ORLADEYO 150 mg (n=21).²

In 16 of the last 17 months of treatment, median attack rate was 0 attacks per month.^{2,a}

SELECT IMPORTANT SAFETY INFORMATION

ORLADEYO at a dose of 150 mg is a moderate inhibitor of CYP2D6 and CYP3A4. For concomitant medications with a narrow therapeutic index that are predominantly metabolized by CYP2D6 or CYP3A4, appropriate monitoring and dose titration is recommended. ORLADEYO at a dose of 300 mg is a P-gp inhibitor. Appropriate monitoring and dose titration is recommended for P-gp substrates (eg, digoxin) when coadministering with ORLADEYO.

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The safety of ORLADEYO[®] is supported by data from patients across 2 clinical studies¹

In APeX-2 part 1, the most common^a treatment-emergent adverse reactions were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease (GERD)¹

Adverse reactions	Placebo (n=39)	ORLADEYO 110 mg (n=41)	ORLADEYO 150 mg (n=40)
	n (%)	n (%)	n (%)
Abdominal pain ^b	4 (10)	4 (10)	9 (23)
Vomiting	1 (3)	4 (10)	6 (15)
Diarrhea ^c	0	4 (10)	6 (15)
Back pain	1 (3)	1 (2)	4 (10)
GERD	0	4 (10)	2 (5)

^a≥10% and higher than placebo.¹

^bIncludes abdominal pain, abdominal discomfort, abdominal tenderness, and upper abdominal pain.¹

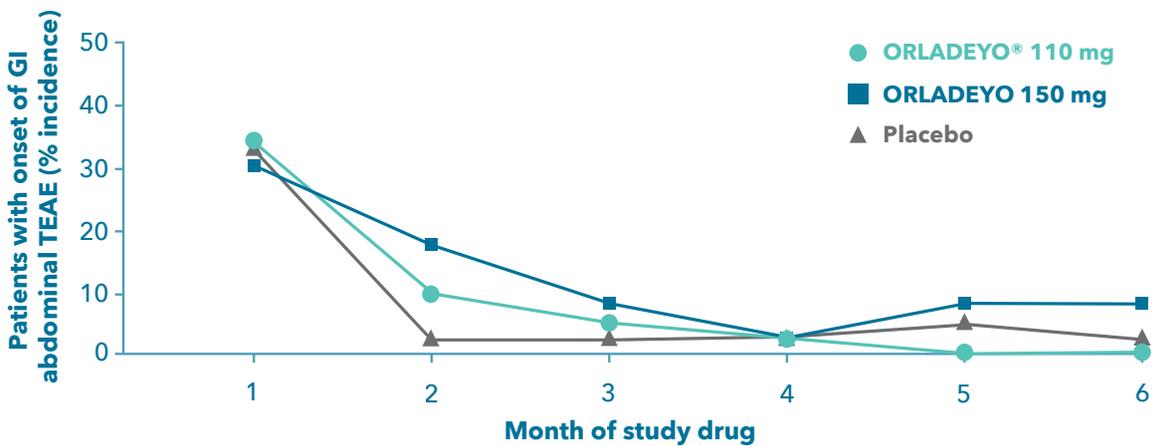
^cIncludes diarrhea and frequent bowel movements.¹

- No patients in the ORLADEYO 150 mg dose group and 1 patient in the ORLADEYO 110 mg dose group discontinued treatment due to a gastrointestinal (GI) adverse reaction in APeX-2 part 1¹
- Findings from the open-label, long-term safety study, APeX-S (interim safety population, n=227), support the data observed in APeX-2 part 1¹
- No new types of side effect were seen in those who continued ORLADEYO for 96 weeks²
 - One patient receiving ORLADEYO 150 mg discontinued treatment due to a GI abdominal adverse reaction in APeX-2 part 3²

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GI adverse reactions generally occurred early after initiation of treatment, became less frequent with time, and typically self-resolved¹

Patients with new-onset GI abdominal TEAEs over time¹³



Patients on study drug:

ORLADEYO 110 mg	41	41	41	41	40	38
ORLADEYO 150 mg	40	40	37	37	37	37
Placebo	39	39	38	37	36	34

Abbreviation: TEAE, treatment-emergent adverse event.

- If GI reactions persist, a reduced dosage of 110 mg once daily with food may be considered¹

Setting expectations with patients regarding possible adverse reactions can help ensure a strong start.⁷

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ORLADEYO[®] demonstrates strong patient retention⁸

Since approval, more than 1500 prescriptions have been written⁸

- Almost half of patients (49.7%) currently on ORLADEYO were previously taking another prophylactic therapy, including injectable prophylaxis^{8,a}



More than 75% of patients who started on ORLADEYO **remained on therapy** for 6 months or longer^{8,a}

^aData current as of March 2022.⁸

It's important to set expectations with patients starting ORLADEYO

- The recommended dosage of ORLADEYO is one 150 mg capsule taken orally once daily with food¹
- Ensure patients have rescue therapy available for treatment of breakthrough HAE attacks¹
- Steady state of ORLADEYO is reached in 6 to 12 days, but it may take longer for patients to experience benefit^{1,11}
 - Encourage patients to check in frequently during the first few weeks of treatment⁴

Many patients are starting—and staying on—ORLADEYO, including those who were previously on injectable prophylaxis.^{8,a}

SELECT IMPORTANT SAFETY INFORMATION

The safety and effectiveness of ORLADEYO in pediatric patients <12 years of age have not been established.

Please see Important Safety Information on page 13 and accompanying full Prescribing Information.

Get your patients started with ORLADEYO[®]

Switching patients should be based on their clinical condition and your discretion⁴

Considerations for patients switching from other prophylactic treatments ⁸	
C1-INH	Discontinue existing C1-INH dosing schedule 14 days after first dose of ORLADEYO. ^a
Lanadelumab-flyo	Day 1 of ORLADEYO dosing to occur on same day as lanadelumab injection. No further dosing of lanadelumab is required after initiating ORLADEYO. ^a
Androgens	BioCryst does not recommend the abrupt discontinuation of androgens.

^aThese recommendations are from the manufacturer of ORLADEYO and are based on clinical trial protocol. They have not been evaluated in a controlled clinical study.⁸

>80%
ATTACK-FREE
MONTHS

Patients who switched to ORLADEYO from lanadelumab or subcutaneous C1-INH remained **attack-free >80%** of the months after switching^{14,c}

- The transition from C1-INH or lanadelumab long-term prophylaxis to monotherapy with ORLADEYO was not associated with additional safety signals^{14,c}

^cThese data are from an analysis of 34 US patients who switched as per the investigator's discretion from an injectable prophylaxis to ORLADEYO (treatment duration, 4 to 12 months) during a long-term safety study (APeX-S).¹⁴

SELECT IMPORTANT SAFETY INFORMATION

There are insufficient data available to inform drug-related risks with ORLADEYO use in pregnancy. There are no data on the presence of berotralstat in human milk, its effects on the breastfed infant, or its effects on milk production.

Please see Important Safety Information on page 13 and accompanying full Prescribing Information.

One stop for all of your ORLADEYO[®] needs⁸

In a qualitative research study of patients who have experience with Empower Patient Services, nearly everyone rated it 10 out of 10 for excellence^{8,a}

Empower Patient Services is known for customer service and care coordinators who truly care. From copay assistance to ORLADEYO shipment coordination—your dedicated care coordinator will be your resource for everything, including



Rapid therapy initiation

- Quick Start program provides access to ORLADEYO during insurance approval process for all insured patients^b
- On average, patients receive their first shipment of ORLADEYO **in less than a week** following submission of the prescription



Comprehensive financial support

- Understanding benefits and insurance approval process
- Reimbursement and financial assistance for all patients, regardless of insurance status
- \$0 copay for commercially insured patients (up to \$40,000 to cover out-of-pocket expenses per calendar year)^c



Personalized HAE and ORLADEYO support

- Single point of contact for you, your office staff, and your patients
- Customized support during transition to ORLADEYO
- Coordination of deliveries
- Ongoing patient support

Give us a call at 1-866-5-EMPOWER (1-866-536-7693) or visit [EmpowerORLADEYOhcp.com](https://www.Oracleyo.com) to learn more about the unique Empower Patient Services experience.

^aThis information was collected and analyzed using a qualitative methodology and a small sample size (N=15). As with all qualitative research, caution should be taken when interpreting these findings.⁸

^bSubject to terms and conditions of the Quick Start program. BioCryst reserves the right to rescind, revoke, or amend the program at any time without notice.

^cSubject to terms and conditions of the copay assistance program. To read the full terms and conditions, visit www.Oracleyo.com/copayassistance. BioCryst reserves the right to rescind, revoke, or amend the program at any time without notice.

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Important Safety Information

INDICATION

ORLADEYO[®] (berotralstat) is a plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older.

Limitations of use

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IMPORTANT SAFETY INFORMATION

An increase in QT prolongation was observed at dosages higher than the recommended 150 mg once-daily dosage and was concentration dependent.

The most common adverse reactions ($\geq 10\%$ and higher than placebo) in patients receiving ORLADEYO were abdominal pain, vomiting, diarrhea, back pain, and gastroesophageal reflux disease.

A reduced dosage of 110 mg taken orally once daily with food is recommended in patients with moderate or severe hepatic impairment (Child-Pugh B or C) and in patients taking chronically administered P-glycoprotein (P-gp) or breast cancer resistance protein (BCRP) inhibitors (eg, cyclosporine).

Berotralstat is a substrate of P-gp and BCRP. P-gp inducers (eg, rifampin, St. John's wort) may decrease berotralstat plasma concentration, leading to reduced efficacy of ORLADEYO. The use of P-gp inducers is not recommended with ORLADEYO.

ORLADEYO at a dose of 150 mg is a moderate inhibitor of CYP2D6 and CYP3A4. For concomitant medications with a narrow therapeutic index that are predominantly metabolized by CYP2D6 or CYP3A4, appropriate monitoring and dose titration is recommended. ORLADEYO at a dose of 300 mg is a P-gp inhibitor. Appropriate monitoring and dose titration is recommended for P-gp substrates (eg, digoxin) when coadministering with ORLADEYO.

The safety and effectiveness of ORLADEYO in pediatric patients <12 years of age have not been established.

There are insufficient data available to inform drug-related risks with ORLADEYO use in pregnancy. There are no data on the presence of berotralstat in human milk, its effects on the breastfed infant, or its effects on milk production.

To report SUSPECTED ADVERSE REACTIONS, contact BioCryst Pharmaceuticals, Inc. at 1-833-633-2279 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, please see the accompanying full Prescribing Information.

One capsule, once per day—this is ORLADEYO®¹



Easy administration

- ORLADEYO is the first and only targeted oral prophylactic therapy for HAE, selectively binding to and inhibiting plasma kallikrein¹
- ORLADEYO is a capsule taken once daily with food¹



Established safety

- ORLADEYO is generally well-tolerated, with long-term safety data and experience^{1,2}
- In APeX-2 part 1, the most common (≥10% and higher than placebo) treatment-emergent adverse reactions were abdominal pain, vomiting, diarrhea, back pain, and GERD¹
- ORLADEYO should not be used for the treatment of acute HAE attacks¹



Sustained attack prevention

- 44% attack rate reduction vs placebo^{1,11,a}
- 50% of patients achieved ≥70% attack rate reduction^{11,b}
- 54% reduction in rescue medication use vs placebo^{11,c}
- 86% attack rate reduction from baseline at week 96^{2,d}



1:1 support

- One dedicated care coordinator will serve as the single point of contact for you, your office staff, and your patients throughout the ORLADEYO journey

There is a strong demand for an oral prophylactic therapy⁶—talk to your patients about adding ORLADEYO to their treatment plan.

^aAPeX-2 part 1 primary efficacy endpoint; $P < 0.001$.¹

^bFrom baseline to week 24, ad hoc analysis; nominal $P = 0.002$.^{1,11}

^cAd hoc analysis; nominal $P < 0.001$.^{8,11}

^dFrom an ad hoc interim analysis of patients who completed 96 weeks of treatment with ORLADEYO 150 mg ($n = 21$).²

SELECT IMPORTANT SAFETY INFORMATION

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References: **1.** ORLADEYO [prescribing information]. Durham, NC: BioCryst Pharmaceuticals Inc.; 2022. **2.** Kiani S, Jacobs J, Desai B, et al. Durable reduction in hereditary angioedema (HAE) attack rates with berotralstat over 24 months: results from the phase 3 APeX-2 study. Presented at: European Academy of Allergy and Clinical Immunology Hybrid Congress; July 10-12, 2021; Madrid, Spain and Krakow, Poland. **3.** Radojicic, C, Riedl MA, Craig TJ, et al. Patient perspectives on the treatment burden of injectable medication for hereditary angioedema. *Allergy Asthma Proc.* 2021;42(3):S4-S10. doi:10.2500/aap.2021.42.210025. **4.** Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. *J Allergy Clin Immunol Pract.* 2021;9(1):132-150.e3. doi:10.1016/j.jaip.2020.08.046. **5.** Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema—the 2017 revision and update. *Allergy.* 2018;73(8):1575-1596. doi:10.1111/all.13384. **6.** Geba D, Sani JM, Gascon M, Hahn R, Aggarwal K, Rosselli J. Hereditary angioedema patients would prefer newer-generation oral prophylaxis. *J Drug Assess.* 2021;10(1):51-56. doi:10.1080/21556660.2020.1863699. **7.** Banerji A, Anderson J, Johnston DT. Optimal management of hereditary angioedema: shared decision-making. *J Asthma Allergy.* 2021;14:119-125. doi:10.2147/JAA.S284029. **8.** Data on file, BioCryst Pharmaceuticals Inc. **9.** Busse PJ, Christiansen SC. Hereditary angioedema. *N Engl J Med.* 2020;382(12):1136-1148. doi:10.1056/NEJMr1808012. **10.** Kaplan AP, Joseph K. The bradykinin-forming cascade and its role in hereditary angioedema. *Ann Allergy Asthma Immunol.* 2010;104(3):193-204. doi:10.1016/j.ana.2010.01.007. **11.** Zuraw B, Lumry WR, Johnston DT, et al. Oral once-daily berotralstat for the prevention of hereditary angioedema attacks: a randomized, double-blind, placebo-controlled phase 3 trial. *J Allergy Clin Immunol.* 2021;148(1):164-172.e9. doi:10.1016/j.jaci.2020.10.015. **12.** Wedner HJ, Aygören-Pürsün E, Bernstein J, et al. Randomized trial of the efficacy and safety of berotralstat (BCX7353) as an oral prophylactic therapy for hereditary angioedema: results of APeX-2 through 48 weeks (part 2). *J Allergy Clin Immunol Pract.* 2021;9(6):2305-2314.e4. doi:10.1016/j.jaip.2021.03.057. **13.** Johnston D, Lumry WR, Banerji A, et al. Gastrointestinal adverse events observed with berotralstat (BCX7353) treatment for hereditary angioedema are primarily mild, self-limited, and diminish with time on treatment. Poster presented at: American Academy of Allergy, Asthma and Immunology Annual Meeting; March 13-16, 2020; Philadelphia, PA. **14.** Riedl MA, Sheridan WP, Noble LJ, Tomita D, Soteres D; APeX-S Study Investigators. Berotralstat demonstrates low hereditary angioedema (HAE) attack rates in patients switching from injectable prophylaxis. Poster presented at: American College of Allergy, Asthma and Immunology Annual Meeting; November 4-8, 2021; New Orleans, LA.

orladeyo[®]
(berotralstat) capsules 150 mg

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