DAWNZERA™ (donidalorsen)

PRODUCT FACT SHEET

About DAWNZERA™ (donidalorsen)

- **DAWNZERA is the first and only RNA-targeted medicine approved by the FDA for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older.**[1]
- **HAE is a rare and potentially life-threatening genetic condition that involves recurrent attacks of severe swelling (angioedema) in various parts of the body, including the hands, feet, genitals, stomach, face and/or throat.**[2–7] Approximately 7,000 people are living with HAE in the United States.[8]
- Discovered and developed by Ionis, DAWNZERA is an RNA-targeted medicine designed to target plasma prekallikrein (PKK), which plays an important role in activating inflammatory mediators associated with HAE attacks.[1] DAWNZERA is designed to limit plasma protein production at the source – in the liver, where it's made.[1,9]
- DAWNZERA is self-administered every four weeks or every eight weeks via autoinjector.[1]
- The most common side effects of DAWNZERA include injection site reactions (such as redness or pain at the injection site), upper respiratory tract infection, urinary tract infection and abdominal discomfort.[1]

Please see Important Safety Information on page 2. Please see full Prescribing Information for DAWNZERA, also available at DAWNZERA.com.

DAWNZERA Clinical Research at a Glance

OASIS-HAE Study Results

Double-Blinded, Placebo-Controlled Study

- The Phase 3 OASIS-HAE study enrolled 90 adult and pediatric patients 12 years of age and older with Type I and Type II HAE.[1]
- Patients were treated with DAWNZERA 80 mg by subcutaneous injection every four weeks (n=45) or every eight weeks (n=23), or placebo (n=22) over 24 weeks.[1]
- DAWNZERA treatment every four weeks significantly reduced monthly HAE attack rate by 81% compared to placebo at Week 24. Mean attack rate reduction increased to 87% compared to placebo when measured from the second dose, a key secondary endpoint.[1]
- Every four-week and every eight-week dosing groups had similar benefits on attack rate reduction at Week 24.[1]

OASISplus Study Results

Open-Label Extension (OLE) and Switch Cohorts

- The ongoing OASISplus study enrolled participants aged 12 and older with Type I or Type II HAE.[10]
- The trial evaluated DAWNZERA 80 mg by subcutaneous injection in two cohorts:[10,11]
  - Patients who completed the OASIS-HAE trial (n=83) and received DAWNZERA every four or eight weeks
  - Patients who switched from prior HAE prophylactic medications to DAWNZERA (n=64) every four weeks
- **Patients in the OLE** had a 94% mean reduction in HAE attacks from baseline after one year of treatment with DAWNZERA.[12]
- **In the switch cohort**, switching to DAWNZERA reduced mean HAE attack rate by 62% from prior treatment at Week 16, with no increases in mean attack rate during the switch.[11]

Across clinical studies, DAWNZERA demonstrated a favorable safety and tolerability profile. The most common adverse reactions (incidence ≥ 5%) were injection site reactions, upper respiratory tract infection, urinary tract infection and abdominal discomfort.[1]

DAWNZERA™ (donidalorsen) 80 mg / 0.8 mL injection

Access to DAWNZERA: Ionis Every Step™

Ionis is committed to helping people access the medicines they are prescribed and will offer a suite of services for people prescribed DAWNZERA through Ionis Every Step. In addition to insurance support and financial assistance programs, Ionis Every Step offers personal support for patients and their doctors. Ionis Patient Education Managers are dedicated partners for patients through every step of the treatment journey.

Visit DAWNZERA.com for more information.

INDICATION

DAWNZERA (donidalorsen) is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

DAWNZERA is contraindicated in patients with a serious history of hypersensitivity reactions, including anaphylaxis, to donidalorsen or any of the excipients in DAWNZERA.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions, including anaphylaxis, have been reported in patients treated with DAWNZERA. If signs and symptoms of serious hypersensitivity reactions occur, discontinue DAWNZERA and institute appropriate therapy.

ADVERSE REACTIONS

Most common adverse reactions (incidence ≥ 5%) are injection site reactions, upper respiratory tract infection, urinary tract infection, and abdominal discomfort.

Please see full Prescribing Information for DAWNZERA, also available at DAWNZERA.com.

References

1. DAWNZERA. Prescribing Information. Ionis Pharmaceuticals.
2. Manning ME. Recognition and management of hereditary angioedema: best practices for dermatologists. *Dermatol Ther (Heidelb)*. 2021;11(5):1829-1838.
3. Valerieva A, Nedeva D, Yordanova V, et al. Therapeutic management of hereditary angioedema: past, present, and future. *Balkan Med J*. 2021;38(2):89-103.
4. Santacroce R, D'Andrea G, Maffione AB, et al. The genetics of hereditary angioedema: a review. *J Clin Med*. 2021;10(9):2023.
5. Pines JM, Poarch K, Hughes S. Recognition and differential diagnosis of hereditary angioedema in the emergency department. *J Emerg Med*. 2021;60(1):35-43.
6. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema - The 2021 revision and update. *Allergy*. 2022;77(7):1961-1990.
7. What is Hereditary Angioedema (HAE). HAEA. (n.d.-b). https://www.haea.org/pages/p/what_is_hae. Accessed June 9, 2025.
8. Busse PJ, Christiansen SC. Hereditary angioedema. *N Engl J Med*. 2020;382(12):1136-1148.
9. Riedl MA, Tachdjian R, Lumry WR, et al. Efficacy and safety of donidalorsen for hereditary angioedema. *N Engl J Med*. 2024;391(1):21-31.
10. Data on file. Ionis Pharmaceuticals.
11. Riedl MA, Bernstein JA, Jacobs JS, et al. Donidalorsen treatment of hereditary angioedema in patients previously on long-term prophylaxis. *J Allergy Clin Immunol Pract*. 2025:S2213-2198(25)00599-9.
12. Data on file. Ionis Pharmaceuticals.