

PATIENT INFORMATION
DAWNZERA™ (dawn-ZAIR-ah)
(donidalorsen)
injection, for subcutaneous use

What is DAWNZERA?

DAWNZERA is a prescription medicine used to prevent hereditary angioedema (HAE) attacks in adults and children 12 years of age and older.

It is not known if DAWNZERA is safe and effective in children under 12 years of age.

Do not use DAWNZERA if you:

- have had a serious allergic reaction, including anaphylaxis to donidalorsen or any of the ingredients in DAWNZERA. See the end of this Patient Information leaflet for a complete list of ingredients in DAWNZERA.

Before using DAWNZERA, tell your healthcare provider about all your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if DAWNZERA can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with DAWNZERA.
- are breastfeeding or plan to breastfeed. It is not known if DAWNZERA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using DAWNZERA.

Tell your healthcare provider about any other medications you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use DAWNZERA?

- Read the detailed Instructions for Use that comes with your DAWNZERA single-dose autoinjector.
- Your healthcare provider will show you and your caregiver how to inject DAWNZERA the first time.
- DAWNZERA is injected under your skin (subcutaneous use) in your stomach area (abdomen) or the front of your upper legs (thighs). Only a healthcare provider or caregiver may give you an injection in the back of your upper arm.
- Use DAWNZERA exactly as your healthcare provider tells you to take it.
- You, your caregiver, or healthcare provider should inject DAWNZERA 1 time every 4 weeks or 1 time every 8 weeks depending on your prescribed dosing frequency.
- If you miss a dose of DAWNZERA, administer the missed dose as soon as possible. Then inject DAWNZERA on the regular dosing schedule from the date of the most recently injected dose.

What are the possible side effects of DAWNZERA?

DAWNZERA can cause serious side effects, including:

- **Allergic reactions.** DAWNZERA can cause allergic reactions. Stop using DAWNZERA and call your healthcare provider or go to your nearest emergency room right away if you have symptoms of serious allergic reaction. Symptoms of serious allergic reaction may include:
 - rash
 - trouble breathing
 - fainting, dizziness, feeling lightheaded (low blood pressure)
 - swelling of your face, lips, or tongue
 - chest pain
 - itching

The most common side effects of DAWNZERA include:

- injection site reactions
- upper respiratory tract infection
- urinary tract infection
- abdominal discomfort

These are not the only possible side effects of DAWNZERA. Tell your healthcare provider if you have any side effect that bothers you or that does not go away while using DAWNZERA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DAWNZERA?

- Store DAWNZERA in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton.
- If needed, DAWNZERA can be stored at room temperature up to 86°F (30°C) in the original carton for up to 6 weeks. If not used within 6 weeks, throw away DAWNZERA.
- Do not freeze.
- Do not expose the autoinjector to heat.
- Protect from direct light.

Keep DAWNZERA and all medicines out of the reach of children.

General information about the safe and effective use of DAWNZERA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DAWNZERA for a condition for which it was not prescribed. Do not give DAWNZERA to other people, even if they have the same symptoms or condition that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about DAWNZERA that is written for health professionals.

What are the ingredients in DAWNZERA?

Active ingredients: donidalorsen

Inactive ingredients: disodium hydrogen phosphate; sodium chloride; sodium dihydrogen phosphate; water for injection; and may include hydrochloric acid or sodium hydroxide. Phosphorous and sodium.

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For more information go to www.DAWNZERA.com or call 1-833-644-6647. If you still have questions, contact your healthcare provider.