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Dawnzera (*donidalorsen*)

An overview of Dawnzera and why it is authorised in the EU

What is Dawnzera and what is it used for?

Dawnzera is a medicine used to prevent hereditary angioedema (swelling) attacks in people aged 12 years and older. People with hereditary angioedema have attacks of rapid swelling that can occur anywhere in the body such as the face, throat, arms, legs or around the gut. These attacks can be life-threatening when swelling around the throat presses against the airway.

Dawnzera contains the active substance donidalorsen.

How is Dawnzera used?

Dawnzera can only be obtained with a prescription. Treatment should be started under the supervision of a doctor experienced in the diagnosis and management of patients with hereditary angioedema.

Dawnzera is given as an injection under the skin once a month. Dawnzera may be given once every 2 months if the patient has had no attacks for at least 3 months during treatment.

The doctor should consider stopping treatment in patients who have normal levels of an enzyme called C1 esterase inhibitor (C1-INH) if the number of attacks they experience is not reduced sufficiently.

For more information about using Dawnzera, see the package leaflet or contact or contact your doctor or pharmacist.

How does Dawnzera work?

In people with hereditary angioedema, blood levels of a protein called kallikrein are abnormally high. This leads to increased levels of another protein called bradykinin which is involved in angioedema attacks.

The active substance in Dawnzera, donidalorsen, is an anti-sense oligonucleotide, a small molecule that targets the messenger RNA (mRNA) which contains instructions for making prekallikrein, a protein necessary for producing kallikrein. This leads to the mRNA being broken down which reduces the blood level of kallikrein and bradykinin and therefore the risk of attacks.

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What benefits of Dawnzera have been shown in studies?

In a main study, Dawnzera has been shown to significantly reduce the number of attacks in people with hereditary angioedema compared with placebo (a dummy treatment).

The main study involved 91 patients from 12 years of age with hereditary angioedema who received Dawnzera (either every 4 weeks or every 8 weeks) or placebo. After 24 weeks, the average number of attacks per month was around 0.4 in patients given Dawnzera every 4 weeks and around 1 for those given Dawnzera every 8 weeks compared with around 2.3 for those given placebo. In addition, the study assessed the impact of treatment on patients' quality of life using a validated questionnaire measuring how the disease symptoms affect people's daily life. Based on responses to this questionnaire, Dawnzera was shown to improve patients' quality of life, compared with placebo.

What are the risks associated with Dawnzera?

For the full list of side effects and restrictions with Dawnzera, see the package leaflet.

The most common side effects with Dawnzera taken every 4 weeks (which may affect more than 1 in 10 people) include injection site reactions such as erythema (reddening of the skin), discolouration, pain, pruritus (itching), induration (hardening), haematoma (collection of blood under the skin), bruising, exfoliation (skin peeling off), hypersensitivity (allergic reactions) and swelling at the injection site.

Why is Dawnzera authorised in the EU?

At the time of approval there was a need for more long-term treatments that prevent breakthrough attacks of hereditary angioedema. Dawnzera given every 4 weeks has been shown to significantly reduce the number of hereditary angioedema attacks compared with placebo. In addition, patients treated with Dawnzera reported an improvement in their quality of life.

Considering the need for effective preventive treatments, the medicine can be used in patients with any type of hereditary angioedema, even though data on the use of Dawnzera in patients who have normal levels of the protein C1-INH are limited.

Data on the safety of Dawnzera are limited due to the rarity of the disease; however, the available evidence shows that Dawnzera's side effects are acceptable.

The European Medicines Agency therefore decided that Dawnzera's benefits are greater than its risks and that it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Dawnzera?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dawnzera have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dawnzera are continuously monitored. Suspected side effects reported with Dawnzera are carefully evaluated and any necessary action taken to protect patients.

Other information about Dawnzera

Dawnzera received a marketing authorisation valid throughout the EU on 19 January 2026.

Further information on Dawnzera can be found on the Agency's website:
ema.europa.eu/medicines/human/EPAR/dawnzera.

This overview was last updated in 12-2025.