13 November 2025
EMA/CHMP/303939/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Dawnzera

donidalorsen

On 13 November 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Dawnzera[2], intended for the routine prevention of recurrent attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older.

The applicant for this medicinal product is Otsuka Pharmaceutical Netherlands B.V.

Dawnzera will be available as an 80 mg solution for injection in pre-filled pens. The active substance of Dawnzera is donidalorsen, a haematological agent (ATC code: not yet assigned). Donidalorsen is an antisense oligonucleotide conjugated to a triantennary N-acetylgalactosamine ($GalNAc_3$) moiety that causes ribonuclease H1-mediated degradation of prekallikrein (PKK) mRNA, which leads to reduced production of PKK protein. PKK is a pro-enzyme for plasma kallikrein, which induces the release of bradykinin, a potent vasodilator causing inflammation and swelling in HAE.

The benefit of Dawnzera is a significant reduction in the HAE attack rate compared with placebo. A phase 3, double-blind, placebo-controlled study showed an 81% reduction in HAE attack rate per 4 weeks from baseline to week 24 with donidalorsen given every 4 weeks compared with placebo. A sustained response, with mean decreases from baseline in the HAE attack rate, was observed throughout the treatment period in the Dawnzera treatment groups. The most common side effects with Dawnzera include injection site reactions, increased hepatic enzyme and hypersensitivity (including anaphylaxis).

The full indication is:

> Dawnzera is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in adults and adolescents aged 12 years and older.

Treatment with Dawnzera is to be initiated under the supervision of a physician experienced in the diagnosis and management of patients with HAE.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.