25 April 2025
EMA/CHMP/134824/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Attrogy

diflunisal

On 25 April 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 Attrogy[2], intended for the treatment of hereditary transthyretin-mediated amyloidosis (ATTRv) in adult patients with stage 1 or stage 2 polyneuropathy.

The applicant for this medicinal product is Purpose Pharma International AB.

Attrogy will be available as 250 mg film-coated tablets. The active substance of Attrogy is diflunisal (ATC code: Salicylic acid and derivatives. ATC code: NO2BA11). Diflunisal stabilises the transthyretin (TTR) tetramer, preventing its dissociation into TTR monomers which are responsible for TTR amyloidosis pathology.

The benefits of Attrogy are its ability to delay disease progression, measured by the Neuropathy Impairment Score plus 7 nerve tests (NIS+7), at 2 years of treatment versus placebo, as shown in a randomised, double-blind, placebo-controlled clinical trial. The most common side effects are gastro-intestinal.

The full indication is:

> Attrogy is indicated for the treatment of hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) in adult patients with stage 1 or stage 2 polyneuropathy.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[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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