25 April 2025
EMA/CHMP/137435/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Amvuttra

vutrisiran

On 25 April 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Amvuttra. The marketing authorisation holder for this medicinal product is Alnylam Netherlands B.V.

The CHMP adopted an extension to an existing indication to include treatment of wild-type or hereditary transthyretin amyloidosis in adults with cardiomyopathy. The full indications for Amvuttra will therefore be as follows:[2]

> Amvuttra is indicated for the treatment of hereditary ~~-mediated~~ transthyretin amyloidosis ~~(hATTR amyloidosis)~~ in adult patients with stage 1 or stage 2 polyneuropathy **(hATTR-PN)**.
>
> **Amvuttra is indicated for the treatment of wild-type or hereditary transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM).**

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to 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] New text in bold, removed text as strikethrough

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