



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2023
EMA/CHMP/331552/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Takhzyro lanadelumab

On 14 September 2023, 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 Takhzyro. The marketing authorisation holder for this medicinal product is Takeda Pharmaceuticals International AG Ireland Branch.

The CHMP adopted an extension to the existing indication as follows:²

TAKHZYRO is indicated for routine prevention of recurrent attacks of hereditary angioedema (HAE) in patients aged ~~12~~**12** years and older.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available 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

