



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

28 January 2021  
EMA/CHMP/50871/2021  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Tysabri natalizumab

On 28 January 2021, 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 Tysabri. The marketing authorisation holder for this medicinal product is Biogen Netherlands B.V.

The CHMP recommended the addition of a new strength (150 mg), a new pharmaceutical form (solution for injection) and a new route of administration (subcutaneous use) for, Tysabri, a multiple sclerosis medicine already authorised for intravenous use. The recommended indication for Tysabri 150 mg solution for injection use (subcutaneous) is the same as the currently authorised indication for Tysabri concentration for solution for infusion.

Treatment with Tysabri is to be initiated and continuously supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions, with timely access to MRI. Home treatment is not recommended.

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.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

