17 September 2026
EMADOC-1829012207-69686
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

VaxRabeo

rabies vaccine (inactivated) for human use

On 17 September 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product VaxRabeo, a vaccine intended for pre-exposure and post-exposure prophylaxis against rabies.

The applicant for this medicinal product is Sanofi Winthrop Industrie.

VaxRabeo will be available as a powder and solvent for suspension for injection. VaxRabeo is a rabies vaccine (ATC code: J07BG01). It contains purified rabies virus (inactivated) strain WISTAR PM/WI38 1503-3M. Administration of VaxRabeo induces the production of neutralising antibodies against the surface glycoprotein of the rabies virus.

The benefit of VaxRabeo is its ability to induce a protective antibody response against the rabies virus in adults and children when used before or after exposure to the virus and as a booster vaccination. In adults, the most frequently reported adverse reactions were injection site pain, myalgia, headache and malaise. In children, the most frequently reported adverse reactions were injection site pain or swelling, myalgia (in children 2 years of age and above), abnormal crying and irritability (in children 12 months to 23 months of age).

The full indication is:

> VaxRabeo is indicated for pre-exposure and post-exposure prophylaxis against rabies in individuals of all age groups.
>
> VaxRabeo should be used in accordance with official recommendations.

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.

[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.

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