



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 February 2026
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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): rotavirus vaccine monovalent (live, oral)

Procedure No. PSUSA/00002665/202507

Period covered by the PSUR:
3 July to 11 July 2025



Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for rotavirus vaccine monovalent (live, oral), the scientific conclusions of PRAC are as follows:

In view of available data on from the literature and spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between rotavirus vaccine monovalent (live, oral) and anaphylactic reaction is at least a reasonable possibility. The PRAC concluded that the product information of products containing rotavirus vaccine monovalent (live, oral) should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for rotavirus vaccine monovalent (live, oral) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rotavirus vaccine monovalent (live, oral) is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.