EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 April 2024
EMA/CVMP/136137/2024
Committee for Veterinary Medicinal Products

Summary of opinion[1] (initial authorisation)

Respivac TRT

Common name: Turkey rhinotracheitis virus, live

On 18 April 2024, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Respivac TRT, lyophilisate for oculonasal suspension/use in drinking water, intended for chickens. The applicant for this veterinary medicinal product is Laboratorios Hipra, S.A.

Respivac TRT is an immunological medicinal product containing avian metapneumovirus subtype B, strain 1062, live (ATCvet code: QI01AD01) as active substance.

The benefit of Respivac TRT is the active immunisation of chickens to reduce the detrimental effect caused by virulent avian metapneumovirus on the ciliary activity, which may be manifested in respiratory clinical signs. The onset of immunity is 3 weeks and the duration of immunity is 9 weeks.

Respivac TRT is generally well tolerated at the recommended dose.

Detailed conditions for the use of this product are described in the summary of product characteristics (SPC) which will be published in the Union Product Database (UPD) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit-risk balance for Respivac TRT and therefore recommends the granting of the marketing authorisation.

[1] Summaries of opinion are published without prejudice to the Commission Decision.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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