20 April 2023
EMA/CVMP/163699/2023
Committee for Veterinary Medicinal Products (CVMP)

Summary of opinion[1] (post-authorisation)

Gumbohatch

Common name: Avian infectious bursal disease vaccine (live)

On 20 April 2023, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal product Gumbohatch. The marketing authorisation holder for this veterinary medicinal product is Laboratorios Hipra, S.A.

Gumbohatch is currently authorised for the active immunisation of 1-day-old broiler chicks and embryonated broiler chicken eggs to reduce clinical signs and lesions of the bursa of Fabricius caused by very virulent avian infectious bursal disease virus (IBDV) infection. The onset of immunity depends on the initial maternally derived antibodies (MDA) level of the batch of chickens and even then, will be different for individual chickens. In practice, studies in commercial broiler chickens have shown an onset of immunity from between 24 days of age and 28 days of age.

Onset of immunity: from 24 days of age.

Duration of immunity: up to 45 days of age.

The variation concerns the amendment of the indication by adding the future layer chickens. Based upon the new data presented investigating efficacy in this subcategory of target species, the onset of immunity (OOI) and duration of immunity (DOI) are split into broiler chickens and future layer chickens, as follows:

Onset of immunity:

Broiler chickens: from 24 days of age.

Future layer chickens: from 29 days of age.

[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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Duration of immunity:

Broiler chickens: up to 45 days of age.

Future layer chickens: up to 71 days of age.

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