EVALUATION OF THE CLINICAL SAFETY AND EFFICACY OF A NEW IN-OVO VACCINE AGAINST AVIAN COCCIDIOSIS (EVANOVO®) UNDER FIELD CONDITIONS

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Keywords: *Eimeria*, gut health, in-ovo vaccination, broilers, coccidiosis

INTRODUCTION

Avian coccidiosis remains one of the most widespread and costly diseases in poultry (Blake *et al.,* 2020). Traditionally, the disease has been controlled using anticoccidial drugs. However, the overuse of these drugs has led to the development of resistance in field *Eimeria* strains (Attree *et al.*, 2021). As a result, researchers and laboratories are constantly searching for and developing new tools to control this disease.
Vaccination against avian coccidiosis is a growing trend worldwide, as it is an efficient tool for restoring sensitivity to anticoccidial drugs (Vereecken *et al.,* 2014) and controlling field *Eimeria* strains (Attree *et al.*, 2021). Recently, (EVANOVO®, HIPRA, S.A.), a live vaccine against avian coccidiosis containing strains attenuated by precociousness and designed for in-ovo (IO) administration, has been launched on the market.
The objective of this multicenter, randomized, double-blind, double-dummy, positive controlled field trial was to evaluate the safety and the efficacy of EVANOVO® when administered under field conditions in a commercial hatchery.

MATERIALS AND METHODS

• Three flocks of broiler chicks reared on three Belgian commercial broiler farms with high oocysts counts were included in the study. The previous batches were treated with a typical shuttle program using anticoccidials as feed additives (narasin + nicarbazin from 0 to 14 days of life, and salinomycin from 14 days of life until slaughter age).
• Vaccinations were performed in a Dutch commercial hatchery using a double-dummy approach after random distribution of the eggs into two groups: Experimental and Positive Control group (Table 1). In the Experimental group, 108,471 eggs were vaccinated IO with EVANOVO® at 18 days of embryonic development. After hatching, the chicks received a placebo via coarse spray at 1 day of age. In the Positive control group, 111,525 eggs were administered a placebo IO at 18 days of embryonic development. After hatching, the chicks were vaccinated via coarse spray with a reference vaccine (EVANT®, HIPRA S.A.) at 1 day of age.
• Once on the farm, the two groups were housed in separate rearing units under identical management conditions and monitored until the end of rearing. Adverse reactions, clinical signs, faeces appearance, productive parameters, mortality rate and intestinal lesions at different timepoints were blindly assessed as safety or efficacy parameters.

Group	18 days of embryonic development	1-day-old chicks
Experimental group products	EVANOVO®	EVANT® placebo**
Positive control group products	Placebo*	EVANT®
Route	*In-ovo*	Coarse spray
Dose	0.05 ml/egg	0.28 ml/bird

Table 1. Scheme of products and vaccination schedule
* Phosphate Buffered Saline
** Solution with the same organoleptic characteristics of EVANT@ solvent without the adjuvanted fraction in order to ensure staining of birds and therefore, maintain blindness at farm level.

• Qualitative variables were analyzed by a Chi Square test. Quantitative variables were analyzed by Student T-test if application conditions were satisfied or alternatively, a Mann-Whitney U-test. The SPSS® (SPSS Inc.) program was used to perform statistical analysis. Values with P≤ 0.05 were considered statistically significant.

RESULTS

SAFETY RESULTS

• No adverse reactions attributable to EVANOVO® were observed.
• There were no statistically significant differences in the hatching rate between groups (Table 2).
• No clinically relevant differences in body weight were detected after hatching and no statistically significant differences were observed at either 3 weeks of age (Table 2).
• Additionally, no clinically relevant intestinal lesions were observed in either group at 1 or 3 weeks of age.

Group	Hatching rate	Body weight (kg)	
		After hatching	3 weeks-old
	%	mean ± SD	mean ± SD
EVANOVO®	94.70	0.045 ± 0.006	0.999 ± 0.137
Positive control	93.47	0.046 ± 0.006	1.004 ± 0.136
p-value	0.615	0.005	0.303

Table 2. Hatching rate and body weight

EFFICACY RESULTS

• No statistically significant differences were observed between groups in the feed conversion rate, body weight at the end of the rearing period, or mortality rate (Table 3).

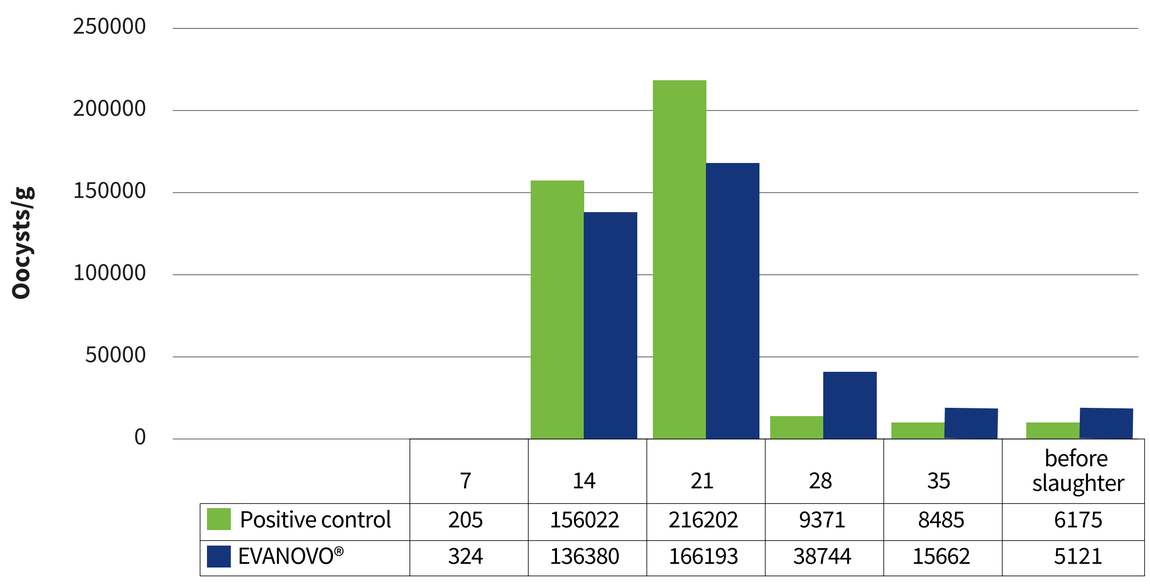
Group	PCR	Body weight at the end of the rearing period (kg)	Mortality rate
	mean ± SD	mean ± SD	%
EVANOVO®	1.57 ± 0.042	2.682 ± 0.351	4.62
Positive control	1.56 ± 0.050	2.671 ± 0.348	4.83
p-value	0.742	0.418	0.870

Table 3. Productive parameters results

• There were no differences between groups in the incidence and severity of intestinal lesions at 4 and 5 weeks of age.
• A similar oocyst count profile was observed in both groups (Graphic 1) because of the vaccination against coccidiosis, indicating proper control of field coccidiosis replication after 3 weeks, as expected in well-immunized flocks and compared with the oocyst counts obtained prior to the vaccination program (Table 4).

Future vaccinated	Mean (oocysts/g)
Future vaccinated Positive control	220,018
Future vaccinated EVANOVO®	140,477

Table 4. Average oocyst counts in litter (after ≥ 28 days) during farm selection in houses using anticoccidial drugs.



Graphic 1. Evolution of oocyst count in litter faeces

CONCLUSIONS

Based on the results obtained, it can be concluded that EVANOVO® is a safe and efficacious vaccine against coccidiosis when administered in-ovo according to the recommended vaccination program under field conditions, comparable to the reference vaccine used as a positive control.

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