

# Safety evaluation of a combined porcine circovirus type 2 and *Mycoplasma hyopneumoniae* vaccine in breeding and lactating sows and gilts



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## INTRODUCTION

Porcine circovirus type 2 (PCV2) is known to be one of the major swine diseases worldwide<sup>1</sup>. It was shown that PCV2 sow vaccination might have a positive effect on sow herd productivity<sup>2</sup>. Boehringer Ingelheim recently licensed Ingelvac CircoFLEX<sup>®</sup> for pregnant and lactating sows. As Ingelvac CircoFLEX<sup>®</sup> is often used in combination with Ingelvac MycoFLEX<sup>®</sup> (not registered for use in sows), it was the objective of this study to determine under field conditions whether the inadvertent application of Ingelvac CircoFLEX<sup>®</sup> mixed with Ingelvac MycoFLEX<sup>®</sup> (FLEXcombo<sup>®</sup>) is safe in pregnant or lactating sows and gilts.

## MATERIALS AND METHODS

The study was designed as randomized, negative controlled, blinded side-by-side study using physiologic saline solution as control product (CP). The farrow-to-finish farm chosen was antibody positive for PCV2 and positive but clinically stable with regard to Porcine reproductive and respiratory syndrome virus. In total, 176 healthy animals (140 sows and 36 gilts) in the 1<sup>st</sup>, 2<sup>nd</sup> or 3<sup>rd</sup> trimester of pregnancy or in lactation were included in the study and vaccinated intramuscularly with a single dose (2 ml) of either FLEXcombo<sup>®</sup> or CP on study day (SD) 0. The parities between the groups were balanced (parity 0 to parity 11).

All sows/gilts were examined by a veterinarian for changes in general health and for local reactions at the injection site on the day of inclusion, on day of vaccination before vaccination, one and four hours post vaccination and daily for 14 days post vaccination. The farrowing data were recorded for each sow within 24 hours after birth of the first piglet. Individual piglet body weights were collected within the first 24 hours post farrowing or SD 1 for the lactation group and at weaning (21±2 days of age).

## RESULTS

Local reactions were observed in both treatment groups. The predominant finding was a reddening of the injection site, which was observed with similar frequency in both groups after vaccination. A transient swelling with a maximum diameter of 1.0 cm was recorded for two vaccinated sows (1<sup>st</sup> trimester). The occurrence of clinical signs like recumbence, reduced appetite or skin scratches post treatment was slightly lower for vaccinated animals (8 out of 88; 9%) than for animals having received the CP (11 out of 88; 13%).

The reproductive performance of the vaccinated animals and the growth of their progeny were not negatively impacted, irrespective of the time of vaccination during pregnancy or lactation (please refer to tables 1 and 2).

**Table 1: Piglets born in total per treatment group and overall**

Group	FLEXcombo <sup>®</sup>		Control product		p-Value
	Mean	95% CI	Mean	95% CI	
1 <sup>st</sup> trimester	13.7	11.4 – 16.1	15.4	13.1 – 17.8	0.1682
2 <sup>nd</sup> trimester	15.7	13.8 – 17.6	16.9	15.4 – 18.4	0.4181
3 <sup>rd</sup> trimester	14.6	13.5 – 15.7	14.0	12.9 – 15.1	0.4841
Overall	14.7	13.7 – 15.7	15.4	14.4 – 16.4	0.3080

**Table 2: Mean average daily weight gain (ADWG) for all piglets weaned within each trimester, lactation group and overall for the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> trimester**

Group	ADWG in kg/d Least Squares Mean		p-Value
	IVP	CP	
1 <sup>st</sup> trimester	0.224	0.208	0.0769
2 <sup>nd</sup> trimester	0.197	0.202	0.5686
3 <sup>rd</sup> trimester	0.228	0.230	0.8502
Lactation	0.248	0.242	0.5471
Overall (1 <sup>st</sup> – 3 <sup>rd</sup> )	0.216	0.214	0.6490

## CONCLUSION

In summary, the application of FLEXcombo<sup>®</sup> was well tolerated. We conclude that the inadvertent application of the associated use of Ingelvac CircoFLEX<sup>®</sup> and Ingelvac MycoFLEX<sup>®</sup> is safe for breeding and lactating sows and gilts under field conditions.

## REFERENCES

1. Fraile, L.; Segalés, J. et al. (2015) Virological and serological characterization of vaccinated and non vaccinated piglet subpopulations coming from vaccinated and non-vaccinated sows. *Preventive Veterinary Medicine* 119 (2015) 153 – 161
2. Misener, M.; Cunningham, G. et al. (2014) Impact on reproductive performance of a sow herd vaccinated with Ingelvac CircoFLEX<sup>®</sup>. *Allen D. Leman Swine Conference*

