Bulletin
TECHNICAL
Boehringer Ingelheim Vetmedica, Inc.

Ingelvac® CircoFLEX™

Vaccine Profile

Porcine Circovirus Type 2 infection and the associated disease (PCVAD) result in severe economic hardship in pig producing areas worldwide. Ingelvac® CircoFLEX™ is a subunit vaccine that is not genetically modified and does not utilize any serum products or animal origin products. The manufacture of Ingelvac® CircoFLEX™ results in the expression of the Open Reading Frame 2 (ORF 2) of the virus genome. ORF 2 encodes for nucleocapsid formation and is the immunogenic portion of the virus.

Efficacy

Ingelvac® CircoFLEX™ is highly effective. Laboratory and field studies have shown significant improvements following the administration of a single dose of Ingelvac® CircoFLEX™ to three week old pigs which were subsequently challenged with PCV2 (Table 1).

Ingelvac® CircoFLEX™ results in significant improvement in:

- **Nasal shedding**
- **Lymphoid depletion**
- **Lymphoid inflammation**
- **Lymphoid immunohistochemistry (IHC) scores**
- **Lung mean lesion scores**

Table 1:
Comparison of Ingelvac® CircoFLEX™ vaccinates and controls following PCV2 challenge

Group	Incident of Lymphoid Depletion	Incident of Lymphoid Inflammation	Incident of Positive Lymphoid IHC	Incident of Lung Inflammation	Incident of Positive Lung IHC	Incident of Nasal Shedding Between Days 32 and 56
Vaccinates	0/21a (0%)	0/21a (0%)	3/21a (14.3%)	0/21a (0%)	0/21a (0%)	9/21a (42.9%)
Controls	16/21b (76.2%)	18/21b (85.7%)	21/2lb (100%)	5/21b (23.8%)	3/21a (14.3%)	20/21b (95.2%)

* Like letters indicate no significant differences (p>0.05)

Decreasing the PCV2 viral load following challenge and decreasing lymphatic tissue pathology, through the use of the Ingelvac® CircoFLEX™ vaccine are important determining factors for preventing development of clinical disease and erosion of profitability. Numerous studies have shown that there was a direct correlation between the quantity of virus present in tissues and serum, and the severity of the disease. In a Canadian study, involving over 3700 pigs, pigs vaccinated at 3 weeks of age and in the presence of maternal immunity showed a significant decrease in mortality.[1]

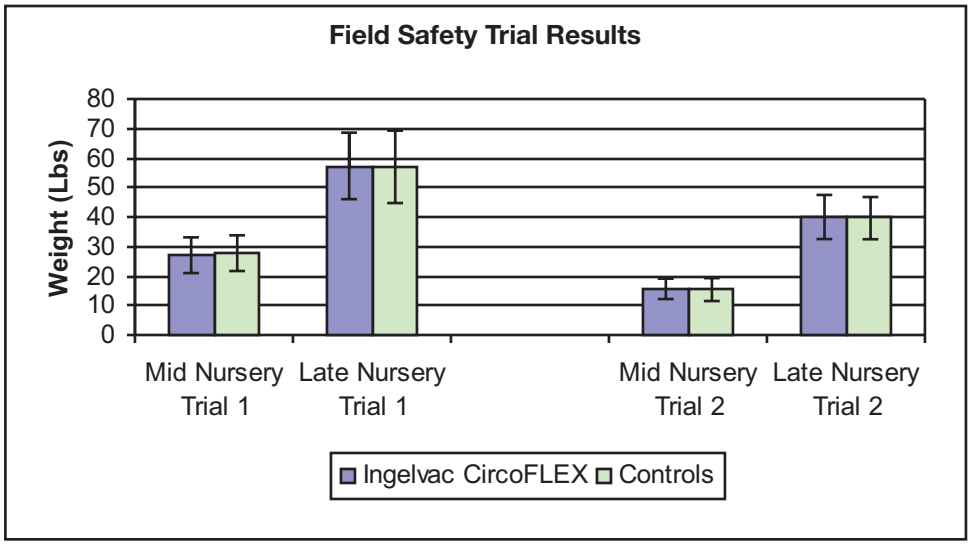
[1] Boehringer Ingelheim Vetmedica, Inc. Data on file. 2006

Safety

Ingelvac® CircoFLEX™ is safe. Injection site lesions have not been observed in laboratory studies when the product was administered according to the label (1 ml intramuscular). No injection site lesions were observed when a 4X overdose was administered, nor has there been any adverse reactions noted following repeated overdoses. Ingelvac® CircoFLEX™ does not result in frequently observed injection site reactions.

In US field studies, involving over 650 pigs from commercial herds not affected by PCVAD, there was no observed adverse clinical signs or injection site reactions following Ingelvac® CircoFLEX™ vaccination. Average daily weight gain was not impaired by vaccination at 3 weeks of age (Figure 1).

Figure 1:
Average weight (lbs) of Ingelvac® CircoFLEX™ vaccinates and controls in commercial herds **not** affected by PCVAD



Summary

Ingelvac® CircoFLEX™ is a very safe and highly effective single dose PCV2 vaccine for protection against PCVAD in swine.