

ENTEROPORC COLI AC



NEW

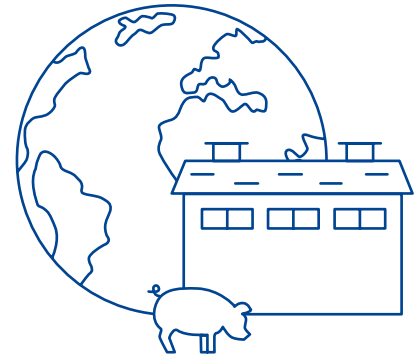
7 IN ONE

**Broadest protection against Neonatal Diarrhoea
caused by *E. coli* and *C. perfringens* type A and C**

Together, beyond animal health



Neonatal Diarrhoea – a challenge for pig farms worldwide



↪ ND occurs during the first days of a piglet's life

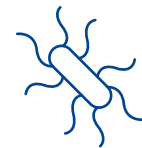


↪ The economic impact by ND with mortality of 10 % can be as high as 134 € per sow per year (Sjolund et al., 2014)



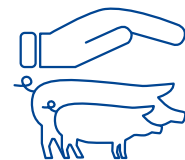
↪ The aetiology is multifactorial

- Enterotoxigenic *E. coli* (ETEC) expressing F4, F5 and F6 fimbrial adhesins
 - *Clostridium perfringens* Type A expressing alpha and beta2 toxin
 - *Clostridium perfringens* Type C expressing beta1 toxin
- are the major pathogens



↪ Management plays a key role

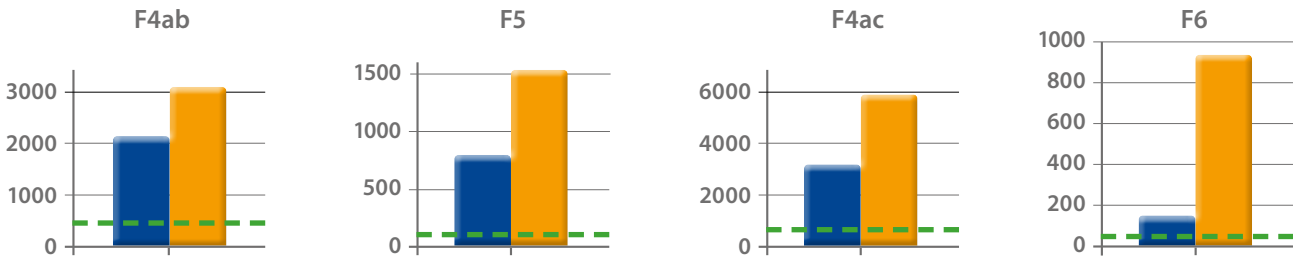
- to keep gilts and sows healthy and in good condition, to avoid outbreaks of other infectious diseases like Influenza or to control MMA
- to boost the antibodies in gilts and sows colostrum by vaccination
- to guarantee newly born piglets ideal environmental conditions and constantly undisturbed suckling during the most sensitive few days after birth



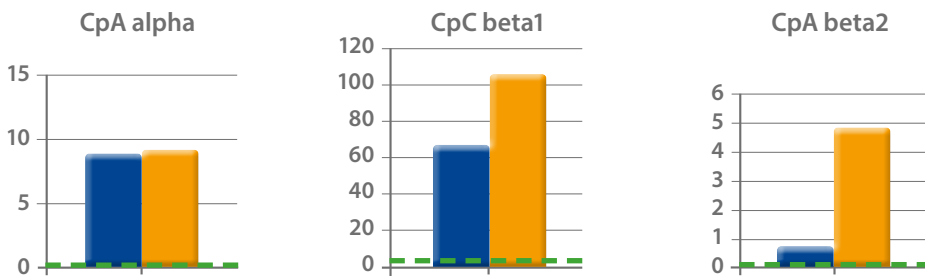
ENTEROPORC COLI AC

induces protective antibody titers

E. coli = rel. OD %



C. perfringens = AU/ml

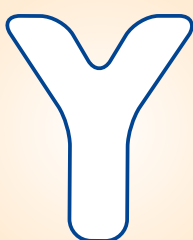


Comparison of mean, protective antibody titers in colostrum of vaccinated gilts following basic (2fold) and sows (3rd) re-vaccination.

Basic vaccination study E1800029, booster vaccination study E1800032

Mortality (*E. coli*) and morbidity (*C. perfringens*) were used as parameters of protection and to determine the protective titers for all antigens using a standardized procedure (ROC analysis, Youden-Index, which provides optimal ratio between specificity and sensitivity).

Antigen	F4ab	F4ac	F5	F6	Alpha-toxin	Beta1-toxin	Beta2-toxin
Protective titer	486 rel. OD %	832 rel. OD %	128 rel. OD %	36 rel. OD %	0.034 AU/ml	5.0 AU/ml	0.005 AU/ml

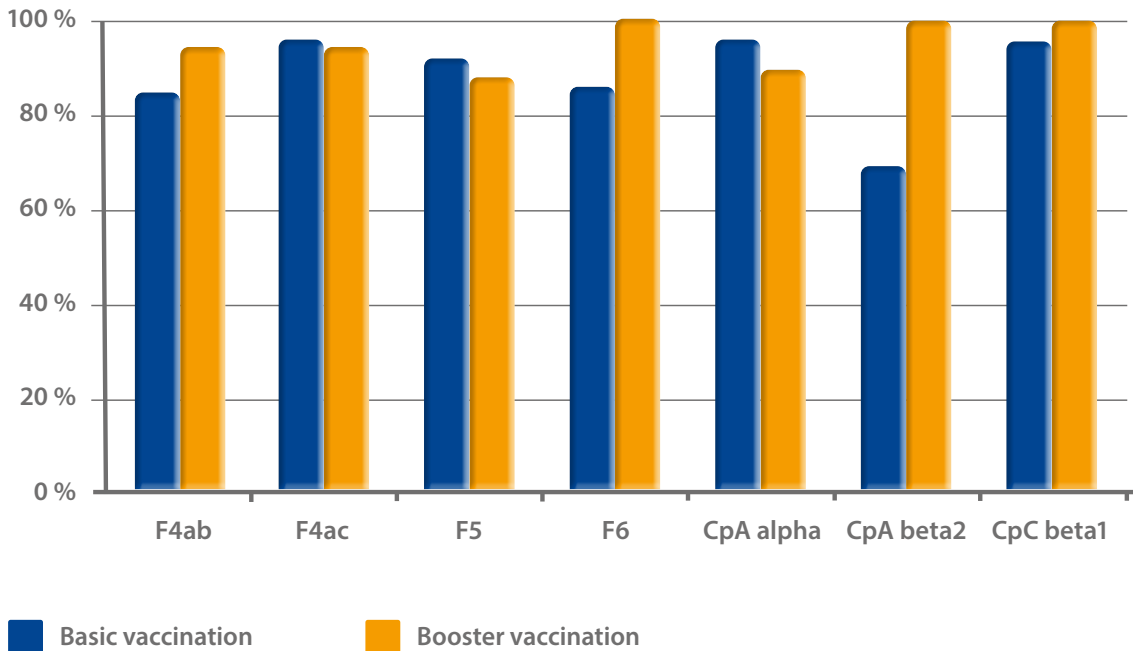


ENTEROPORC COLI AC induces protective antibodies against all seven antigens, relevant in ND.

ENTEROPORC COLI AC

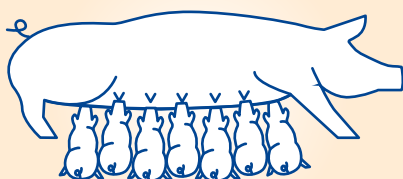
boosts antibodies after re-vaccination

Percentage of gilts/sows with antibody titers in colostrum equal to or above the protective titer



Basic vaccination study E1800029, booster vaccination study E1800032

The efficacy of a **third vaccination** with **ENTEROPORC COLI AC** in sows administered **2 weeks before the second farrowing** under field conditions was assessed by antibody titers and compared with the titers of gilts vaccinated twice (basic immunization). **Antibodies either reached the same level or were even boosted.**



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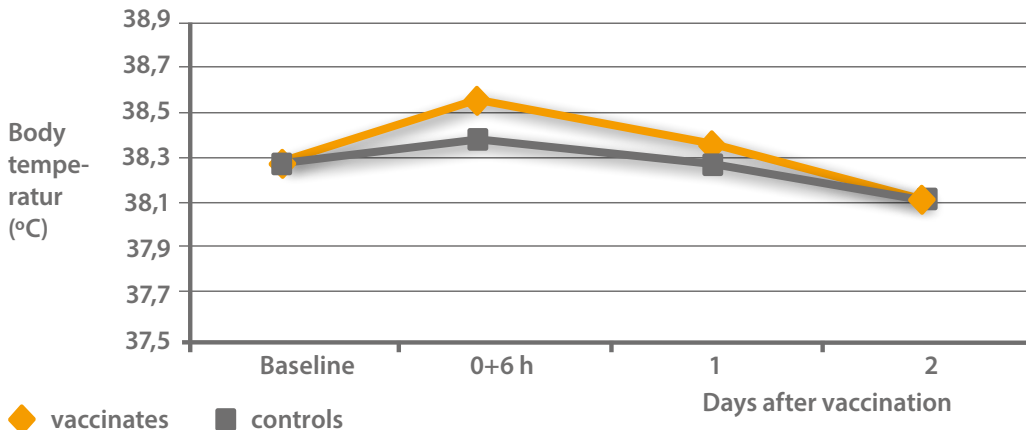
boosts antibodies in sows
colostrum after re-vaccination.

ENTEROPORC COLI AC

is safe for sows and gilts

Aluminium hydroxide-based adjuvant: long lasting immunity, induction of high IgG titers, excellent safety profile

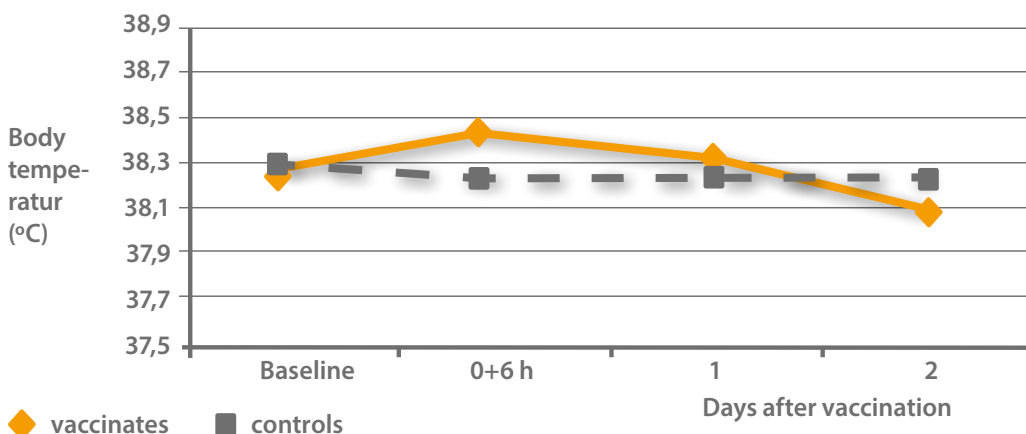
Mean rectal body temperature after basic vaccination of pregnant gilts



The mean rectal body temperature of the vaccinates peaked 6 h post second vaccination with increase of 0.25°C and returned to normal within 24 hours.

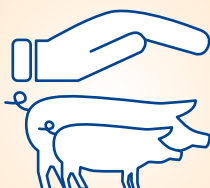
A slightly depressed behaviour on the day of vaccination was recorded very commonly in the 3 field studies for registration. A slight redness and slight swelling at the injection site was observed very commonly which resolved within a week post administration. There was no significant difference between the treatment groups for any reproductive performance variable.

Mean rectal body temperature after booster vaccination in pregnant sows



The mean rectal body temperature of the animals in both groups was slightly increased after vaccination, however remained at all time points within the physiological range.

Basic vaccination study E1800021, booster vaccination study E1800027



ENTEROPORC COLI AC
is safe for sows and gilts in the most sensitive period of late pregnancy.

ENTEROPORC COLI AC

Broadest protection against Neonatal Diarrhoea caused by *E. coli* and *C. perfringens* type A and C

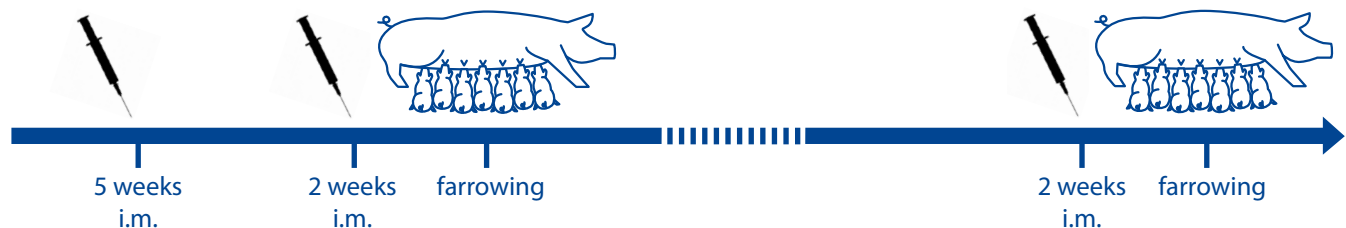
Seven *E. coli* and Clostridia antigens in one vaccine including ***C. perfringens* Type A, α and β 2 toxoid**

UNIQUE

- reduces mortality and morbidity
- ensures more and thriving piglets weaned
- saves time and effort



Vaccination scheme



Enteroporc Coli AC registration dossier studies: E1800019; E1800021; E1800027; E1800032
CVMP assessment report for Enteroporc Coli AC (EMA/V/C/005149/0000) EMA/557738/2020

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Enteroporc COLI AC lyophilisate and suspension for suspension for injection for pigs **Composition:** One dose (2 ml) contains Active substances: Lyophilisate: *Clostridium perfringens* type A/C toxoids: alpha toxoid \geq 125 IU/ml*, beta1 toxoid \geq 3354 IU/ml*, beta2 toxoid \geq 794 IU/ml*. Suspension: Inactivated fimbrial adhesins of *Escherichia coli*: F4ab \geq 23 IU/ml*, F4ac \geq 19 IU/ml*, F4c \geq 13 IU/ml* and F6 \geq 37 IU/ml*. Adjuvant: Aluminium (as hydroxide) 2.0 mg/ml. **Indication:** For the passive immunisation of progeny by active immunisation of pregnant sows and gilts to reduce: - Clinical signs (severe diarrhoea) and mortality caused by *E. coli* strains expressing the adhesins F4ab, F4c, F5 and F6; - Clinical signs (diarrhoea) during the first days of life associated with *Clostridium perfringens* type A expressing alpha and beta2 toxins; - Clinical signs and mortality associated with haemorrhagic and necrotizing enteritis caused by *Clostridium perfringens* type C expressing beta1 toxin. Onset of immunity (after uptake of colostrum): *E. coli* F4ab, F4c, F5, F6: within 12 hours after birth. *C. perfringens* type A and C: First day of life. **Contraindications:** None. **Adverse reactions:** A transient increase in body temperature (mean 0.5 °C, in individual pigs up to 2 °C) occurred very commonly on the day of vaccination which returned to normal within 24 hours. A transient swelling and redness at the injection site (mean 2.8 cm, in individual pigs up to 8 cm) was very commonly observed which disappeared without treatment within 7 days. A slightly depressed behaviour was commonly observed on the days of vaccination. **Withdrawal period:** Zero days. **To be supplied only on veterinary prescription. Marketing Authorisation Holder:** Ceva Santé Animale, 10, av. de la Ballastière, 33500 Libourne, France * toxoid content and fimbrial adhesins content in relative units per ml, determined in ELISA against an internal standard.