Erysipelothrix Rhusiopathiae Bacterin

For use in swine only

ER Bac® Plus

PRODUCT DESCRIPTION: ER Bac Plus is for vaccination of healthy swine 3 weeks of age or older as an aid in preventing disease caused by *Erysipelothrix rhusiopathiae* for a period of 20 weeks following the second dose in the vaccination regimen. ER Bac Plus is a liquid, serum-free, clarified bacterin that has been chemically inactivated and combined with the adjuvant Amphigen® to enhance the immune response.

DISEASE DESCRIPTION: Erysipelas is caused by the bacterium *E. rhusiopathiae* and has been identified as a pathogen in swine since 1878. The disease is worldwide in distribution and is of economic importance throughout Europe, Asia, Australia, and North and South America. Swine 3 months through 3 years of age are most susceptible to erysipelas; outbreaks are usually more severe in herds on soil and during periods of wet weather. Erysipelas can take one of several forms or a combination of the following forms. **Acute erysipelas** is a general infection by *E. rhusiopathiae* in the bloodstream. This form often causes sudden death. Abortion may result in sows infected during pregnancy. **Skin erysipelas** manifests as diamond-shaped patches of swollen, purple skin on a pig's body, especially the belly and thighs. If the tips of the ears and tail are affected, tissues may die and slough. **Arthritic erysipelas** is a chronic disease occurring in pigs that have survived acute erysipelas. Affected pigs often have swollen and stiff joints. They do not gain weight efficiently, and their carcasses are often trimmed or condemned by inspectors at packing houses. **Cardiac erysipelas** usually occurs in older pigs raised on farms where the chronic form exists. Cardiac erysipelas may result in growths on the heart valves altering the normal flow of blood.

SAFETY AND EFFICACY: In laboratory and field safety studies of ER Bac Plus, no serious adverse reactions to vaccination were reported. Efficacy of ER Bac Plus was demonstrated in 2 host animal studies conducted by Zoetis Inc.; an immunogenicity study and a duration-of-immunity study demonstrating efficacy 20 weeks after second vaccination. Pigs vaccinated with ER Bac Plus, followed by challenge, had significantly fewer clinical signs of disease, including death, lesions, and fever, than nonvaccinated control pigs in both of the following studies. **Host animal immunogenicity study:** The purpose of this study was to demonstrate protection against challenge with virulent *E. rhusiopathiae* 2 1/2 weeks after the second vaccination. Pigs were vaccinated at approximately 3 and 6 weeks of age. Pigs were monitored daily for rectal temperature and for clinical signs of disease. Ten of 10 control pigs (100%) were determined to be positive for infection after challenge. Nineteen of 20 vaccinated pigs (95%) were protected. These results indicate that vaccination with ER Bac Plus with Amphigen provided significant protection from challenge 2 1/2 weeks after vaccination. (Tables 1 and 2).

Table 1. Results of *E. rhusiopathiae* Challenge in Control Pigs (100% positive).

Control Pigs	2 days*	1 day only	Clinical signs**	Mortality/ Euthanasia	Treated	Organism isolation
10	7	3	8	3	7	3

* Elevation in rectal temperature above 40.9°C (105.6°F) on 2 consecutive days.
** Clinical signs included recumbent, depressed, and/or metastatic skin lesions.

Table 2. Results of *E. rhusiopathiae* Challenge 2 1/2 Weeks Postvaccination (95% protected).

Vaccinated Pigs	2 days*	1 day only	Clinical signs**	Mortality/ Euthanasia	Treated	Organism isolation
20	1	0	0	0	1	Not Sampled

* Elevation in rectal temperature above 40.3°C (104.6°F) on 2 consecutive days.
** Clinical signs included recumbent, depressed, and/or metastatic skin lesions.

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Duration-of-immunity study: The purpose of this study was to demonstrate protection against challenge with virulent *E. rhusiopathiae* in a duration-of-immunity study 20 weeks after the second vaccination or at approximately market weight (26 weeks of age). Pigs were vaccinated at approximately 3 and 6 weeks of age. Pigs were monitored daily for rectal temperature and for clincial signs of disease. Nine of 10 control pigs (90%) were determined to be positive for infection after challenge. Fifteen of 20 vaccinated pigs (75%) were protected. These results indicate that vaccination with ER Bac Plus with Amphigen provided significant protection from challenge 20 weeks after vaccination. (Tables 3 and 4).

Table 3. Results of *E. rhusiopathiae* Challenge in Control Pigs (90% positive).

Control Pigs	2 days*	1 day only	Clinical signs**	Mortality/ Euthanasia	Treated	Organism isolation
10	3	4	9	7	3	5

* Elevation in rectal temperature above 40.9°C (105.6°F) on 2 consecutive days.
** Clinical signs included recumbent, depressed, and/or metastatic skin lesions.

Table 4. Results of *E. rhusiopathiae* Challenge in 26-week-old Pigs (75% protected).

Vaccinated Pigs	2 days*	1 day only	Clinical signs**	Mortality/ Euthanasia	Treated	Organism isolation
20	3	5	5	1	4	1

* Elevation in rectal temperature above 40.3°C (104.6°F) on 2 consecutive days.
** Clinical signs included recumbent, depressed, and/or metastatic skin lesions.

DIRECTIONS:

1. *General Directions:* Shake well. Aseptically administer 2 mL intramuscularly.
2. *Primary Vaccination:* Healthy swine 3 weeks of age or older should receive two 2-mL doses administered 3–4 weeks apart.
3. *Revaccination:* Semiannual revaccination with a single dose is recommended.
4. Good animal husbandry and herd health management practices should be employed.

PRECAUTIONS:

1. Store at 2°–7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.
2. Use entire contents when first opened.
3. Sterilized syringes and needles should be used to administer this vaccine.
4. Do not vaccinate within 21 days before slaughter.
5. As with many vaccines, anaphylaxis may occur after use. Initial antidote of epinephrine is recommended and should be followed with appropriate supportive therapy.
6. This product has been shown to be efficacious in healthy animals. A protective immune response may not be elicited if animals are incubating an infectious disease, are malnourished or parasitized, are stressed due to shipment or environmental conditions, are otherwise immunocompromised, or the vaccine is not administered in accordance with label directions.

Technical inquiries should be directed to Zoetis Inc. Technical Services, (888) 963-8471 (USA), (800) 461-0917 (Canada).

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