

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.

REFERENCES:

1. Gois M, Kuksa F, Sisak F: Microbial findings in the lungs of slaughter pigs. *Proc 6th Int Congr Pig Vet Soc*, Copenhagen, 6:214, 1980.
2. Yamamoto K, Ogata M: Mycoplasmal and bacterial flora in the lungs of pigs. *Proc 7th Int Congr Pig Vet Soc*, Mexico City, 7:94, 1982.
3. Ross, RF: Mycoplasmal Diseases. In: Straw BE, D'Allaire S, Mengling WL, et al. (eds.) *Diseases of Swine*, 8th Edition, pp. 495-509. ISU Press, Ames, Iowa USA.
4. Wood RL: Erysipelas. In: Straw BE, D'Allaire S, Mengling WL, et al. (eds.) *Diseases of Swine*, 8th Edition. Ames, Iowa: Iowa State University Press, 419-430, 1999.

Technical inquiries should be directed to Zoetis Inc.

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Zoetis Inc.

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Erysipelothrix Rhusiopathiae- Mycoplasma Hyopneumoniae Bacterin

For use in swine only

RespiSure¹ONE[®]/ER Bac Plus[®]

PRODUCT DESCRIPTION: RespiSure-ONE/ER Bac Plus is for vaccination of healthy swine, including pregnant sows and gilts, 3 weeks of age or older as an aid in preventing erysipelas caused by *Erysipelothrix rhusiopathiae* for a period of 20 weeks and respiratory disease caused by *Mycoplasma hyopneumoniae* for a period of 25 weeks. RespiSure-ONE/ER Bac Plus is a liquid preparation of a chemically inactivated whole cell culture of *M. hyopneumoniae* and a serum-free, clarified *E. rhusiopathiae* culture, plus Amphigen[®], a unique oil-in-water adjuvant to enhance the immune response.

DISEASE DESCRIPTION: Mycoplasmal pneumonia of swine (MPS), or enzootic pneumonia, is a widespread, chronic disease characterized by coughing, growth retardation, and reduced feed efficiency. The etiologic agent is *M. hyopneumoniae*; however, the naturally occurring disease often results from a combination of bacterial and mycoplasmal infections.

MPS causes considerable economic loss in all areas where swine are raised. Surveys conducted at various locations throughout the world indicate that lesions typical of those seen with MPS occur in 30%-80% of slaughter-weight swine. Because mycoplasmal lesions may resolve before hogs reach slaughter weight, the actual incidence may be higher. The prevalence of *M. hyopneumoniae* infection in chronic swine pneumonia has been reported to range from 25%¹-93%.² Pigs of all ages are susceptible to MPS, but the disease is most common in growing and finishing swine. Current evidence indicates that *M. hyopneumoniae* is transmitted by aerosol or direct contact with respiratory tract secretions from infected swine. Transmission from sow to pig during lactation is possible.³ Once established, MPS occurs year after year in infected herds, varying in severity with such environmental factors as season, ventilation, and concentration of swine.

Clinical signs of MPS include a chronic, nonproductive cough continuing for weeks or months, unthriftiness, and retarded growth, even though the appetites of infected swine remain normal. Stunting may occur,

resulting in considerable variation in size among affected pigs. Death loss associated with secondary bacterial infection and stress may occur.

M. hyopneumoniae causes a loss of ciliary motility in the bronchial passages. Eventually the cilia are destroyed, resulting in reduction in natural defense in the upper respiratory tract and increased susceptibility to secondary infection with bacterial agents such as *Pasteurella multocida*, *Haemophilus parasuis*, *Actinobacillus pleuropneumoniae*, and *Bordetella bronchiseptica*. Swine lungworm and roundworm larvae infections may also increase the severity of MPS.

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.⁴

SAFETY AND EFFICACY: The safety of RespiSure-ONE/ER Bac Plus was demonstrated in 3 field safety studies conducted in 3 different geographic locations. Nine hundred and six pigs were vaccinated at approximately 3 and 6 weeks of age. No injection site reactions or serious systemic reactions were observed following vaccination.

The efficacy of RespiSure-ONE/ER Bac Plus as an aid in preventing pneumonia caused by *M. hyopneumoniae* was demonstrated in host animal challenge studies conducted by Zoetis Inc. Duration-of-immunity studies demonstrated protection against challenge with virulent *M. hyopneumoniae* up to 25 weeks after a single vaccination in pigs as young as 3 weeks of age. In all studies,

vaccinated pigs had significantly lower lung lesion scores than pigs receiving a placebo.

Table 1. *Mycoplasma hyopneumoniae* Efficacy Studies

Study	Treatment	No. of Pigs	Vaccination (age in wks)	Challenge (wks after vacc)	Challenge (age in wks)	% Lung Lesion
1	Placebo RespiSure-ONE/ ER Bac Plus	23	3	7	10	9.9 ^a
		24	3	7	10	1.8 ^b
2	Placebo RespiSure-ONE	20	3	18	21	13.2 ^a
		19	3	18	21	5.5 ^b
3	Placebo RespiSure-ONE	19	3	23	26	9.0 ^a
		22	3	23	26	2.1 ^b
4	Placebo RespiSure-ONE	26 [*]	1	25	26	4.5 ^a
		22 [*]	1	25	26	2.0 ^b
5	Placebo RespiSure-ONE	24	1	25	26	5.9 ^a
		20	1	25	26	0.3 ^b

^{a,b} Within each study group, values with different superscripts are statistically significant vs. placebo ($P \leq 0.05$).

* Pigs were serologically positive for *M. hyopneumoniae*.

Host animal studies were also conducted to demonstrate the efficacy of RespiSure-ONE/ER Bac Plus in preventing disease caused by *E. rhusiopathiae*. Pigs were vaccinated at approximately 3 and 6 weeks of age and challenged at either 4 or 20 weeks post-second vaccination. Pigs were monitored daily for rectal temperature and for clinical signs of disease. In both studies, vaccination provided significant protection from challenge.

Table 2. *Erysipelothrix rhusiopathiae* Efficacy Studies

Study	Treatment	No. of Pigs	Challenge (wks after vacc)	Percent of animals with clinical signs of disease
1	Placebo RespiSure-ONE/ ER Bac Plus	10	4	100
		19	4	0
2	Placebo ER Bac Plus	10	20	90
		20	20	25

DIRECTIONS:

- General Directions:** Vaccination of all pigs on the premises is recommended to enhance herd immunity. Shake well. Aseptically administer 2 mL intramuscularly.
- Primary Vaccination:** Administer a single 2-mL dose to healthy swine 3 weeks of age or older, followed by a single dose of ER Bac Plus approximately 3 weeks later. In young pigs, vaccinate after maternally derived antibodies to *E. rhusiopathiae* have declined.
- Revaccination:** Semiannual revaccination with a single dose is recommended.
- Good animal husbandry and herd health management practices should be employed.

PRECAUTIONS:

- Store at 2°–7°C. Prolonged exposure to higher temperatures may adversely affect potency. Do not freeze.