

# ZOETIS INC.

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## RespiSure 1 ONE®

### Zoetis

#### Mycoplasma Hyopneumoniae Bacterin

*For use in swine only*

**PRODUCT DESCRIPTION:** RespiSure-ONE is for vaccination of healthy swine 1 day of age or older as an aid in reducing chronic pneumonia caused by *Mycoplasma hyopneumoniae*. Duration of immunity in 1-day-old pigs has not been established.

RespiSure-ONE is a liquid preparation of a chemically inactivated whole cell culture of *M. hyopneumoniae*, coupled with a unique oil adjuvant Amphigen®, to enhance and prolong the immune response without causing detectable tissue damage at the injection site.

**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%<sup>1</sup>-93%.<sup>2</sup> 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.<sup>3</sup> 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, unthrifty appearance, 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.

**SAFETY AND EFFICACY:** In clinical studies conducted by Zoetis Inc., RespiSure- ONE has been shown to be safe and free from significant adverse reactions when administered according to label directions. Chemical inactivation renders RespiSure-ONE incapable of causing infectious disease. The oil-base adjuvant in RespiSure-ONE does not produce the major tissue damage sometimes associated with conventional oil adjuvants.

Efficacy of RespiSure-ONE was demonstrated in host animal studies conducted by Zoetis Inc.; duration-of-immunity studies demonstrated efficacy up to 25 weeks after a single vaccination in pigs as young as 1 week of age. In all of these duration-of-immunity studies, pigs vaccinated with RespiSure-ONE, followed by challenge, had significantly lower lung lesion scores than pigs vaccinated with a placebo.

**Duration-of-immunity studies:** The purpose of the 7 studies below in Table 1 was to demonstrate protection against challenge with virulent *M. hyopneumoniae* 8, 18, 23 or 25 weeks after a single vaccination with RespiSure-ONE in 1-, 3-, or 8-week-old pigs. All pigs were necropsied and lung lesion scores determined (percent of total lung with lesions<sup>4</sup>). In all cases pigs vaccinated with RespiSure-ONE had significantly lower lung lesion scores than pigs vaccinated with a placebo. Duration of immunity in 1-day-old pigs has not been established.

**Table 1.**

Study	Treatment	No. of Pigs	Vaccination (age in wks)	Challenge (wks after vacc)	Challenge (age in wks)	% Lung Lesion
1	Placebo	22	3	8	11	2.7 <sup>a</sup>
	RespiSure-ONE	24	3	8	11	0.1 <sup>b</sup>
2	Placebo	20	3	18	21	13.2 <sup>a</sup>
	RespiSure-ONE	19	3	18	21	5.5 <sup>b</sup>
3	Placebo	18	8	8	16	10.3 <sup>a</sup>
	RespiSure-ONE	20	8	8	16	0.5 <sup>b</sup>
4	Placebo	21	8	18	26	9.6 <sup>a</sup>
	RespiSure-ONE	20	8	18	26	0.9 <sup>b</sup>
5	Placebo	19	3	23	26	9.0 <sup>a</sup>
	RespiSure-ONE	22	3	23	26	2.1 <sup>b</sup>
6	Placebo	26*	1	25	26	4.5 <sup>a</sup>
	RespiSure-ONE	22*	1	25	26	2.0 <sup>b</sup>
7	Placebo	24	1	25	26	5.9 <sup>a</sup>
	RespiSure-ONE	20	1	25	26	0.3 <sup>b</sup>

<sup>a,b</sup> Within each study group, values with different superscripts are statistically significant vs. placebo (p 0.05).

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

**DIRECTIONS:**

1. *General Directions:* Shake well. Aseptically administer 2 mL intramuscularly.
2. *Primary Vaccination:* Administer a single 2-mL dose to healthy swine 1 day of age or older. RespiSure-ONE may also be given as two 1-mL doses administered 2 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.

**REFERENCES:**

1. Gois M, Kuksa F, Sisak F: Microbiological findings in the lungs of slaughter pigs. *Proc 6<sup>th</sup> Int Congr Pig Vet Soc*, Copenhagen. 6:214, 1980.
2. Yamamoto K, Ogata M: Mycoplasmal and bacterial flora in the lungs of pigs. *Proc 7<sup>th</sup> Int Congr Pig Vet Soc*, Mexico City. 7:94, 1982.
3. Clark LK: Stalling mycoplasma. *Hog Farm Management*. p. 56, Oct 1988.
4. Pointon AM, Mercy AR, Backstrom L, Dial GD: Surveillance at Slaughter. In AD Leman, Straw BE, Mengeling WL, *et al.* (eds.) *Diseases of Swine*, 7<sup>th</sup> Edition, p 975. ISU Press, Ames Iowa USA.

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

For veterinary use only

U.S. Veterinary License No.190

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**Presentation:** 50 dose (100 mL), 250 dose (500 mL), and 500 dose (1,000 mL) bottles.

**CPN:** 3690034.5