

For Animal Use Only

RESPISURE- ONE™

Reg. No. G2374 Act 36/1947

For use by or under the control of a veterinarian only

INDICATIONS:

RespiSure-One™ is for vaccination of healthy swine 3 weeks of age and older as an aid in preventing chronic pneumonia caused by *Mycoplasma hyopneumoniae*.

STORAGE INSTRUCTIONS:

Store between 2 °C and 7 °C. Do not freeze. Prolonged exposure to higher temperatures and/or direct sunlight may adversely affect potency.

COMPOSITION:

RespiSure-One™ is a liquid preparation of a chemical 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.

WARNINGS:

Do not vaccinate within 21 days before slaughter.

Keep out of reach of children, uninformed persons and animals.

As with most vaccines, anaphylaxis may occur after use. Initial antidote of adrenalin is recommended and should be followed with appropriate supportive therapy.

Transient local swelling at injection site may occur following vaccination.

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.

Good animal husbandry and herd health management practices should be employed.

Although this vaccine has been tested extensively under a large variety of conditions failure thereof may ensue as a result of a wide range of reasons. If this is suspected, seek veterinary advice and notify the registration holder.

PRECAUTIONS:

Use entire contents when first opened.

Sterilized syringes and needles should be used to administer this vaccine. Do not sterilize with chemicals because traces of disinfectant may inactivate the vaccine.

Burn containers and all unused contents.

DOSAGE AND DIRECTIONS FOR USE:

General Directions:

Vaccination of healthy, piglets is recommended. Shake well. Aseptically administered 2 ml **RespiSure-One™** intramuscularly.

Primary Vaccination: Administer a single 2 ml **RespiSure-One™** dose to healthy swine 3 weeks of age or older.

Revaccination: Semiannual revaccination with a single dose of **RespiSure-One™** is recommended.

DISEASE DESCRIPTION:

Mycoplasma pneumoniae of swine (MPS) or enzootic pneumonia is a widespread, chronic disease

characterised 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 mycoplasma 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 mycoplasma 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 % - 93 %. 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, 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 infected 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 infections 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.

EFFICACY:

In clinical studies conducted by Pfizer Animal Health, **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-based 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 Pfizer; duration-of-immunity studies demonstrated efficacy up to 23 weeks after a single vaccination in pigs as young as 3 weeks 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 placebo.

DURATION-OF-IMMUNITY STUDIES:

The purpose of the 5 studies (Table 1) was to demonstrate protection against challenge with virulent *M. hyopneumoniae* 8, 18 or 23 weeks after a single vaccination with **RespiSure-One™** in 3- or 8-week old pigs. All pigs were necropsied and lung lesion scores determined (percent of lung with lesions). In all cases pigs vaccinated with **RespiSure-One™** had significantly lower lung lesion scores than pigs vaccinated with a placebo.

Table 1:

Study	Treatment	No. of Pigs	Vaccination (age in weeks)	Challenge (wks after vacc)	Challenge (age in weeks)	% lung Lesion
1	Placebo	22	3	8	11	2.7
	RespiSure-One	24	3	8	11	0.1
2	Placebo	20	3	18	21	13.2
	RespiSure-One	19	3	18	21	5.5
3	Placebo	18	8	8	16	10.3
	RespiSure-One	20	8	8	16	0.5
4	Placebo	21	8	18	26	9.6
	RespiSure-One	20	8	18	26	0.9
5	Placebo	19	3	23	26	9.0
	RespiSure-One	22	3	23	26	2.1

PRESENTATION:

100 ml, 500 ml and 1 000 ml vials.
(50, 250 or 500 dose vials).

REGISTRATION HOLDER:

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