

Swine Influenza Vaccine, H1N1 and H3N2

Killed Virus

For use in swine only

FluSure™

PRODUCT DESCRIPTION: FluSure is for vaccination of healthy swine 3 weeks of age or older as an aid in preventing respiratory disease caused by swine influenza virus (SIV) subtypes H1N1 and H3N2. FluSure is a freeze-dried preparation containing 2 type A field isolates, subtypes H1N1 and H3N2, of inactivated swine influenza viruses grown on an established cell line. A sterile diluent containing Amphigen®, a unique oil-in-water adjuvant to enhance the immune response, is used to rehydrate the freeze-dried vaccine.

DISEASE DESCRIPTION: Swine influenza (SI) is an acute respiratory disease caused by Type A influenza viruses. In the USA, 2 subtypes of SIV (H1N1 and H3N2) have emerged as the major disease-causing agents. SIV is a common component of the porcine respiratory disease complex (PRDC). A typical outbreak of respiratory disease caused by SIV is characterized by sudden onset and rapid spread within herds.

Clinical signs include depression, anorexia, coughing, fever (105–107°F/40.5–41.7°C) and serous discharge from the eyes and nose. The duration of the disease is usually 5–7 days. While clinical signs can be severe, recovery is generally rapid and death loss is usually less than 1%.

However, SIV does predispose animals to secondary infections. The virus multiplies in the epithelial cells lining the bronchi and bronchioles causing necrosis of these cells.¹ Gross lung lesions appear firm and purple and are indistinguishable in many cases from *Mycoplasma hyopneumoniae* lesions. Laboratory testing is required for definitive diagnosis.

Nose-to-nose contact is the primary mode of transmission. Inhalation of contaminated aerosol particles is another possible means of transmission. Tentative diagnosis of SI may be based on clinical signs, gross lesions at necropsy, and the widespread prevalence of respiratory disease in the herd. Confirmation of infection may be based on either antibody presence or viral isolation. Good herd hygiene and proper facility maintenance are important in managing SI. There is no specific treatment for SI, but supportive care may be helpful.

SAFETY AND EFFICACY: The safety of FluSure 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.

Efficacy of FluSure was demonstrated in 2 host animal challenge studies. Pigs were vaccinated at 3–15 days of age and again 14 days later. Sixteen days following the second vaccination, the pigs were challenged with a heterologous isolate of either SIV H1N1 or H3N2. Pigs were necropsied 5 days postchallenge and lung damage evaluated. As compared to nonvaccinated controls, pigs vaccinated with FluSure had significantly lower rectal temperatures, clinical signs, and lung lesion scores following challenge with either SIV H1N1 or H3N2. Study results are presented in Tables 1–4.

H1N1 Challenge Study:

Table 1. H1N1 serum hemagglutination inhibition geometric mean titers

	Day 0*	Day 14	Day 28	Day 35
Controls	5.0**	5.0	5.0 ^a	11.7 ^a
Vaccinates	5.2	5.7	49.5 ^b	49.4 ^b

* Day 0 = Day of first vaccination

** Titers of < 10 were factored as 5.0 in calculation of geometric mean titers.

^{a,b}Geometric mean titers within the same column with different lower-case superscripts are significantly different.

Table 2. Mean percent lung damage and frequency of clinical signs

	Mean percent lung damage*	Frequency of animals with at least 1 clinical sign** postchallenge
Controls	23.41 ^a	9/18 ^a
Vaccinates	5.04 ^b	0/19 ^b

* Back-transformed least-squares means

** Depression and/or rapid breathing and/or persistent coughing

^{a,b}Geometric mean titers within the same column with different lower-case superscripts are significantly different.

H3N2 Challenge Study:

Table 3. H3N2 serum hemagglutination inhibition geometric mean titers

	Day 0*	Day 14	Day 28	Day 35
Controls	5.0**	5.0 ^a	5.9 ^a	9.7 ^a
Vaccinates	5.0	7.5 ^b	267.2 ^b	166.3 ^b

* Day 0 = Day of first vaccination

** Titers of < 10 were factored as 5.0 in calculation of geometric mean titers.

^{a,b}Geometric mean titers within the same column with different lower-case superscripts are significantly different.

Table 4. Mean percent lung damage and frequency of clinical signs

	Mean percent lung damage*	Frequency of animals with at least 1 clinical sign** postchallenge
Controls	33.43 ^a	13/20 ^a
Vaccinates	0.65 ^b	0/19 ^b

* Back-transformed least-squares means

** Depression and/or rapid breathing and/or persistent coughing

^{a,b}Geometric mean titers within the same column with different lower-case superscripts are significantly different.

A study evaluating the duration of immunity of the H3N2 component of FluSure is in progress.

DIRECTIONS:

1. *General Directions:* Vaccination of all pigs on the premises is recommended to enhance herd immunity. Shake diluent before use. Aseptically rehydrate the freeze-dried vaccine with

the accompanying adjuvant-containing sterile diluent, shake well, and administer 2 mL intramuscularly.

2. *Primary Vaccination:* Healthy swine 3 weeks of age or older should receive two 2-mL doses administered approximately 3 weeks apart. In young pigs, vaccinate after maternally derived antibodies to SIV have declined.

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 or rehydrated.

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. Easterday BC, Van Reeth K: Swine Influenza. In: Straw BE, D’Allaire S, Mengling WL, *et al.* (eds.) *Diseases of Swine*, 8th Edition, pp. 277–290. ISU Press, Ames, Iowa USA.

Technical inquiries should be directed to Pfizer Animal Health Veterinary Services, (800) 366-5288 (USA), (800) 461-0917 (Canada).

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Pfizer Anima Health
Exton, PA 19341, USA
Div. of Pfizer Inc
NY, NY 10017

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