See productdata/aphis.usda.gov for a summary of the studies approved by the USDA for licensing this product. This package insert also contains additional information developed by the licensee. This license is conditional. Potency and efficacy test studies are in progress.

POLYPRENYL IMMUNOSTIMULANT

U.S. Vet. Prod. No. 9380.00 U.S. Veterinary License No. 637

INDICATIONS

The product has been shown to be effective for the treatment of cats 8 weeks of age or older against rhinotracheitis. For more information regarding efficacy and safety, see productdata.aphis.usda.gov.

DESCRIPTION

Polyprenyl Immunostimulant is a 2 mg/ml solution of disodium salt of a homologous series of phosphorylated polyisoprenols with three trans- and an increasing number (7-9) of cis-isoprene isomers; its structure is shown here:

-o¯) Na⁺ Ò Na

where 3 = number of trans-, 7-9 = number of cis- isomers; 1-2 = number of phosphoric anions It is a colorless, clear liquid.

DOSAGE AND ADMINISTRATION

The dose is 0.5 mg/kg (0.25 ml/kg) administered orally, twice daily for 15 days. Restricted to use by a veterinarian.

FELINE VIRAL RHINOTRACHEITIS

Feline viral rhinotracheitis (FVR) is a common upper respiratory disease in cats, caused by herpesvirus. Because FVR is very contagious, cats in multi-cat environments are at high risk of exposure to the virus. Cats of all ages may get infected. Chronic nasal and ocular problems often occur after herpesvirus infection.

The common signs of FVR are sneezing, loss of appetite, runny nose, watery eyes, conjunctivitis (inflammation of the tissues surrounding the eye, especially the lining of the lids and the third eyelid) and eye discharge, excessive salivation, mouth breathing, and lethargy.¹

EFFICACY IN RHINOTRACHEITIS

Thirty-eight 6- to 11-week old, specific pathogen-free cats of both sexes were enrolled into a placebo-controlled, randomized, double-blinded virus challenge study. The cats were challenged with feline rhinotracheitis virus. Twenty randomly selected animals (experimental group) received 0.25 ml/kg (0.5mg/kg) of Polyprenyl Immunostimulant orally twice daily on days 0 through 14 days post-challenge (DPC); the other eighteen cats (placebo group) received an equal amount of placebo solution. The cats were examined for clinical signs daily, and clinical scores (0 = Absence, 1 = Moderate, clear, serous, 2 = Severe, mucopurulent) were recorded daily. An animal was considered affected by FVR if a score of \geq 1 for clinical signs of either rhinitis or conjunctivitis was present for one or more days.

Treatment	Number of animals with	
	Maximum Score = 1	Maximum Score = 2
Polyprenyl Immunostimulant	11	9
Placebo	3	15

SAFETY²

Safety studies in 390 owned cats total were conducted at 24 sites in 10 states comprising 3 geographical regions. Cats' ages ranged from 2 days to 16 years including 128 cats < 8 weeks of age. 0.5 mg/kg of Polyprenyl Immunostimulant was administered to the cats orally twice daily for 15 days. Adverse events were minimal, being confined to 3 animals reacting to the taste of the product and one animal having diarrhea.

The product has not been tested in pregnant animals. Do not mix with other products. Preservative: Amphotericin B.

SHIPPING AND STORAGE

Polyprenyl Immunostimulant is shipped in individual vials of 10 ml or in packages of 6 vials. Store at 2-8 °C (35 – 46 °F). Must not be frozen: freezing and thawing may cause precipitation of the product from the solution.

²Legendre AM et al (2017) Frontiers Vet. Sci. doi: 10.3389/fvets.2017.00024, <u>https://www.frontiersin.org/article/10.3389/fvets.2017.00024</u>



Manufactured by: Sass & Sass, Inc. 115A Flint Rd., Oak Ridge, TN 37830, 865-481-6000 U.S. Veterinary License # 637 Helping the body fight disease

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¹Gaskell RM, Dawson S, Radford A. Feline respiratory disease, p. 151-162 In: Sykes J and Greene CE Infectious Diseases of The Dog And Cat, 4th Ed., 2011, Elsevier, St. Louis, MO.