SYNOPLEX- poly(n-acetyl, n-arginyl)glucos amine (50000-80000 mw) powder, for solution Synedgen, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Synoplex® (poly(acetyl, arginyl) glucosamine) Wound Rinse, 1g

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For topical use on animals in the family Elephantidae and Rhinocerotidae only. Not intended for oral, parenteral, or ocular administration.

NOT APPROVED BY FDA - Legally marketed as an FDA Indexed Product under MIF 900-012. Extralabel use is prohibited.

Note---In order to be legally marketed, an animal drug product intended for a minor species must be Approved, Conditionally Approved, or Indexed by the FDA. THIS PRODUCT IS INDEXED.

It is a violation of Federal law to use this product in a manner other than as directed in the labeling.

NET CONTENTS: 1 g poly(acetyl, arginyl) glucosamine/amber glass bottle

DESCRIPTION

Derived from chitin obtained from Arctic shrimp shells, Synoplex® has an approximate molecular weight of 20 to 100 kDa. Each gram of Synoplex® contains 1 gram of poly (acetyl, arginyl) glucosamine. Synoplex® is supplied as a dry soluble powder, that is rehydrated with sterile water prior to use. Synoplex® acts on the bacterial membrane causing aggregation of bacteria and pore formation leading to reduction of viable bacteria and prevention of biofilm formation.

Synoplex Bottle Label



INDICATION

For topical application on animals in the family Elephantidae and Rhinocerotidae for treatment of foot and dermal lesions infected with aerobic or facultative anaerobic Gram-positive and/or Gram-negative bacteria; and for treatment of sterile chronic foot and dermal lesions.

IFOR USE IN ANIMALS IN THE FAMILY ELEPHANTIDAE AND RHINOCEROTIDAE ONLY; THIS PRODUCT IS NOT TO BE USED IN ANIMALS INTENDED FOR USE AS FOOD FOR HUMANS OR OTHER ANIMALS.

WARNING

Not for use in humans. Keep out of the reach of children. In case of skin, eye contact, or ingestion, flush affected area with water. If inhalation occurs and breathing becomes difficult, move to fresh air, and contact a physician.

OTHER HEALTH INFORMATION

Poly (acetyl) glucosamine can be characterized as biologically safe, nontoxic, biocompatible and biodegradable polysaccharide. The publicly available toxicology and safety data adequately support the safety of poly (acetyl) glucosamine in terms of general toxicity in animals and *in vitro* and local tolerance studies. A series of general toxicology tests were also conducted to provide additional assurance that poly (acetyl, arginyl) glucosamine did not show differences from the safety profile of poly (acetyl) glucosamine. The results from these studies in rodents showed no test article-related changes in hematology or clinical chemistry, and no microscopic lesions associated with administration of poly (acetyl, arginyl) glucosamine. in a L5178Y TK +/- mouse lymphoma forward mutation screen, poly (acetyl, arginyl) glucosamine was also negative for induction of mutagenic activity after treatment for 4 hours with and without S9, and for 24 hours without S9.

To obtain a Material Safety Data Sheet, call Synedgen, Inc. at (909) 447-6858.

DOSAGE AND ADMINISTRATION

Synoplex® is supplied as a dry soluble powder, needing to be rehydrated with sterile water prior to use. Wear gloves during handling and use of Synoplex®. Determine the amount of Synoplex® powder needed to achieve the desired concentration for the intended use. Dissolve Synoplex® in a known volume of sterile water and mix well. Before applying rinse treatment, ensure that the lesion is properly debrided.

CLEANLINESS

It is recommended that application vessels should be clean prior to use.

DOSE

A general dose of Synoplex® for infected wounds is 500µg/mL and for non-infected wounds is 200µg/mL in a volume sufficient to moisten the affected area. The frequency of application should be 1-2 times per day until the lesion is resolved. Synoplex® should always be used in conjunction with good wound care consisting of initial debridement to remove all necrotic and/or infected tissue.

DOSE CALCULATION

The possible doses are calculated below.

	Synoplex Powder		Synoplex Dosage		Amount of Sterile Water
Example: 1)	1g	X	200 μg/mL	=	5L
Example: 2)	1g	X	500 μg/mL	=	2L

PRECAUTION

Synoplex® efficacy against *Mycobacteria* sp. has not been demonstrated. No information is available concerning use on juvenile, pregnant or nursing animals.

HOW SUPPLIED

Synoplex® is supplied as a dry soluble powder in amber glass bottles containing 1-gram of poly (acetyl, arginyl) glucosamine. Synoplex® is packaged in cartons containing either one (1) bottle or five (5) bottles of 1-gram of poly (acetyl, arginyl) glucosamine.

STORAGE and HANDLING

Store dry soluble powder at 25 °C (77°F) temperature for up to 1 year. Reconstituted solution can be stored for up to 6 months at 2-8 °C (36-46 °F).

QUESTIONS/COMMENTS?

For technical assistance, call Synedgen Inc. at (909) 447-6858. To report an adverse event, call Synedgen Inc. at (909) 447-6858, or FDA at 1-888-FDA-VETS.

Manufactured by:

Synedgen

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Claremont, CA 91711

(909) 447-6858

Patent No: 8,119,780B2

SYNOPLEX

poly (acetyl, arginyl) glucosamine powder, for solution

Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG LABEL	Item Code (Source)	NDC:42368- 500	
Route of Administration	TOPICAL	DEA Schedule		

	Active Ingredient/Active Moiety				
I	Ingredient Name	Basis of Strength	Strength		
	POLY(N-ACETYL, N-ARGINYL)GLUCOSAMINE (50000-80000 MW) (POLY(N-ACETYL, N-ARGINYL)GLUCOSAMINE (50000-80000 MW))	POLY(N-ACETYL, N-ARGINYL)GLUCOSAMINE (50000-80000 MW)	1 g in 1 g		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:42368-500-05	5 in 1 CARTON				
1	NDC:42368-500-01	1 in 1 CARTON				
1	NDC:42368-500-00	1 g in 1 BOTTLE, GLASS				

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
Legally Marketed Unapproved New Animal Drugs for Minor Species	MIF900012	03/11/2013		

Labeler - Synedgen, Inc. (830276353)

Establishment				
Name	Address	ID/FEI	Business Operations	
Synedgen, Inc.		830276353	api manufacture, manufacture, analysis, label, pack	

Revised: 3/2013 Synedgen, Inc.