NDC Number: 42368-500-00

Synoplex®

(poly (acetyl, arginyl) glucosamine)

Wound Rinse

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 ï Legally marketed as an FDA Indexed Product under MIF 900-012.
Extra-label 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.

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.

FOR 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 a 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 the 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 500 µg/mL and for non-infected wounds is 200 µg/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
Examples:	1) 1 g	X	200 µg/mL	=	5 L
	2) 1 g	X	500 µg/mL	=	2 L

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 ºC (77ºF) temperature for up to 1 year. Reconstituted solution can be stored for up to 6 months at 2-8 ºC (36-46 ºF).

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

1420 N. Claremont Blvd. Suite 105 D
Claremont, CA 91711
(909) 447-6858
www.synedgen.com

Patent No: 8,119,780 B2

BOTTLE LABEL

CARTON LABEL – 1 PACK

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

Not intended for oral, parenteral or ocular administration.

Not for use in animals intended for human consumption.

Lot:_____

Exp:_____

PART No: REV:

NDC # 42368-500-00 Rx Only

Synoplex®

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

CARTON CONTAINS: 1 VIAL OF 1 g DRY POWDER

Manufactured by: Synedgen, Inc. 1420 N Claremont Blvd Suite 105 D
Claremont, CA 91711 (909) 447-6858 www.synedgen.com

Patent No: 8,119,780 B2

Indication: Synoplex® is for topical application on animals in the family Elephantidae and Rhinocerotidae for foot and dermal lesions.

Directions: Supplied as a dry powder, rehydrate with sterile water prior to use. For complete directions, see package insert.

Warnings: Not for use in humans

Store at 25 °C (77°F).

KEEP OUT OF REACH OF CHILDREN.

CARTON LABEL – 5 PACK

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

Not intended for oral, parenteral or ocular administration.

Not for use in animals intended for human consumption.

Lot:_____

Exp:_____

PART No: REV:

NDC # 42368-500-00 Rx Only

Synoplex®

(poly (acetyl, arginyl) glucosamine) 5x1 g
Wound Rinse

CARTON CONTAINS: 5 VIALS OF 1 g DRY POWDER

Manufactured by: Synedgen, Inc. 1420 N Claremont Blvd Suite 105 D
Claremont, CA 91711 (909) 447-6858 www.synedgen.com

Patent No: 8,119,780 B2

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