

TRIS-NAC- acetylcysteine solution

Nextmune AB

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.

Tris-NAC™

N-ACETYLCYSTEINE ANTIBACTERIAL solution with high ionic strength for dogs and cats.

Active ingredient(s):

N-Acetylcysteine 1.35 %.

Inactive ingredient(s):

deionized water, EDTA, ethylhexylglycerin, PEG-40 hydrogenated castor oil, phenoxyethanol, propylene glycol, silica, Tris.

Indications:

Tris-NAC™ is an innovative and synergistic combination of NAC and Tris-EDTA to be applied as an effective support to prevent bacterial biofilm formation. Where a mature biofilm already exists, Tris-NAC™ works to disrupt it and break it down.

Warnings:

- **For external use only, not indicated for oral use.**
- Store the unopened bottle at room temperature and keep away from sunlight.
- Keep out of reach of children.
- Dispose of empty bottle properly.

Shelf life of the reconstituted suspension in a refrigerator (36° to 46°F): 2 months

How to use:

- Unscrew the cap from the bottle.
- Insert other cap, after removing silver film.
- Fully press so that powder can be dispensed in the bottle.
- Shake well the bottle.
- Using syringe (contained in the pack), withdraw from the bottle the quantity as described below or as your veterinarian directs.

In the ear canal: dispense the contents of the syringe into the ear canal and gently massage the base of the ear. On the skin: soak a sterile gauze with the product and hold the gauze to the skin for at least 2 minutes. In the case of larger areas, put the product directly on the skin until completely soaked. In both cases, do not rinse or dry. Repeat the application when necessary, or as your veterinarian directs.

See the package leaflet for further information.

Distributor:
nextmune

Nextmune US, LLC

2801 S. 35th St., Phoenix,
AZ 85034 - 480-464-8971

Made
in **Germany**

Manufacturer

icf™

Evolution of
Knowledge
a division of nextmune

NEXTMUNE ITALY S.R.L.

Via G.B. Benzoni, 50 26020

PALAZZO PIGNANO (CR) Italy

Tel. +39 0373 982024 +39 0373 938345

e-mail: info@icfsrl.it - customercare@drnsrl.it

PRINCIPAL DISPLAY PANEL - 120 ml Bottle Carton

Tris-NAC™

Solution

N-ACETYLCYSTEINE

ANTIBACTERIAL

solution with high
ionic strength

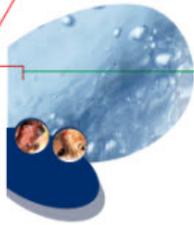
for dogs and cats

Developed in Italy

icf™

Evolution of
Knowledge

4.05 fl. oz. (120 ml)



EXP DATE: XX
LOT: XX

IB0448/01

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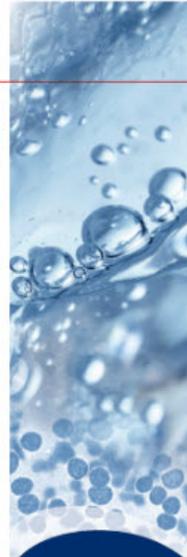
Made
in Germany

Manufacturer
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admission of **nextmune**

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Tris-NAC™



Solution

N-ACETYLCYSTEINE
ANTIBACTERIAL
solution with high
ionic strength
for dogs and cats



Developed in Italy

ICP
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Knowledge

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TRIS-NAC

acetylcysteine solution

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:86127-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETYLCYSTEINE (UNII: WYQ7N0BPYC) (ACETYLCYSTEINE - UNII:WYQ7N0BPYC)	ACETYLCYSTEINE	1.35 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
EDETIC ACID (UNII: 9G34HU7RV0)	
WATER (UNII: 059QF0KO0R)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PEG-40 CASTOR OIL (UNII: 4ERD2076EF)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
TROMETHAMINE (UNII: 023C2WHX2V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86127-011-07	1 in 1 CARTON		
1		120 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		06/01/2022	

Labeler - Nextmune AB (352950223)

Establishment

Name	Address	ID/FEI	Business Operations
NEXTMUNE Italy SRL		435856461	MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
PharmaZell GmbH		506639652	API MANUFACTURE

