CLX DERM OTO PLUS- chlorhexidine gluconate 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.

CLXDerm[™] oto plus

oto plus Chlorhexidine digluconate ear cleanser for cats and dogs.

Properties: ClxDerm[™] oto plus Chlorhexidine digluconate ear cleanser is an otic antiseptic solution designed for cleaning and moisturizing the ears of dogs and cats while providing a protective barrier against dirt and secretions that can attract bacteria. Contains moisturizers to help relieve itching. Chlorhexidine digluconate, the active ingredient in ClxDerm[™] oto plus Chlorhexidine digluconate ear cleanser, has been proven effective against a broad-spectrum of micro-organisms sensitive to chlorhexidine. The use of ClxDerm[™] oto plus will aid in the management of skin infections, supporting a healthy skin barrier.

Directions for use: Apply a few drops of the product into each ear canal and then gently message the base of the ear to spread the solution. Allow the solution to remain in the ear for several minutes before removing. Then, use a clean cotton ball to remove dirt or waxy build-up. No need to rinse ears. Allow the ear to dry after each treatment. May be applied 1-2 times per week or as directed by your veterinarian.

Composition:

ACTIVE INGREDIENT(S):

Chlorhexidine digluconate 0.15%.

INACTIVE INGREDIENT(S):

1,2-Hexanediol, Caprylyl glycol, Fragrance, Glycerophosphoinositol lysine salt, Lactobionic acid, Propylene glycol, Purified water.

Precautionary statements:

For external use in the ear canals of dogs and cats only. May cause skin or eye irritation. Avoid getting solution in your pet's eyes. In case of contact with eyes, rinse thoroughly with water and consult a veterinarian. If skin irritation occurs and persists, discontinue use and contact your veterinarian. Consult a veterinarian before using on pregnant, lactating or breeding animals; puppies; kittens; or animals with a pre-existing medical condition. Use with caution in older animals. Do not use in animals with damaged eardrums. If an animal has an adverse reaction to treatment, discontinue use and contact your veterinarian.

Warning: Keep out of reach of children.

Storage: Store at room temperature.

Do not freeze.

www.icfpet.com

Distributor: Nextmune US, LLC

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

made in **Spain**

Manufacturer: iCF™ Evolution of Knowledge a division of 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

To KNOW MORE ABOUT plus



PRINCIPAL DISPLAY PANEL - 150 ml Bottle Carton

CLXDerm™

oto plus

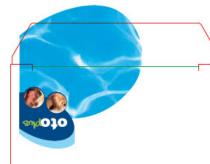
Chlorhexidine digluconate ear cleanser for cats and dogs

Developed in Italy

iCF™

Evolution of Knowledge

5.07 fl. oz.(150 ml)



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IB0447/01

CLX Dermi otoplus

Chlorhexidine dicluconate ear cleanser

digluconate ear cleanser for cats and dogs Precautionary statements: For external use in the ear canals of dogs and cats only. May cause skin or eye irritation. Avoid getting solution in your pet's eyes. In case of contact with eyes, rinse thoroughly with water and consult a veterinarian. If skin irritation occurs and persists, discontinue use and contact your veterinarian. Consult a veterinarian before using on pregnant, lactating or breeding animals; puppies; kittens; or animals with a pre-existing medical condition. Use with caution in older animals. Do not use in animals with damaged eardrums. If an animal has an adverse reaction to treatment, discontinue use and contact your veterinarian.

Warning: Keep out of reach of children. Storage: Store at room temperature. Do not freeze.

Distributor:

Nextmune US, LLC 2801 S. 35th St., Phoenix, AZ 85034 made 480-464-8971 in Spain





NEXTRONE FIALY S.R.L. Via G.B. Berzoni, 50 26020 PALAZZO PIGNANO (CR) Italy Tel. +39 0373 982024 + +39 0373 938345 e-mail: Intro@jlofari.ti oustomercare@jdmcr1.tt





Developed in Italy

Chlorhexidine digluconate

ear cleanser

for cats and doos



Evolution of Rnowledge



CLX DERM OTO PLUS

chlorhexidine gluconate solution

Product Informa	tion							
Product Type		OTC ANIMAL DRUG	ltem Co	Item Code (Source)		NE	NDC:86127-002	
Route of Administr	AURICULAR (OTIC)							
Active Ingredien	t/Active	Moiety						
Ingredient Name Basis of Streng								Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - CHLORHEXIDINE - UNII: R4K00DY52L) CHLORHEXIDINE GLUCONATE							5 mg n 1 mL	
Inactive Ingredie	ents							
		Ingredient Nam	е				Strength	
water (UNII: 059QF0K00R)								
GLYCEROPHOSPHOINOSITOL LYSINE (UNII: X34K43QI7A)								
PROPYLENE GLYCOL	(UNII: 6DC9	Q167V3)						
LACTOBIONIC ACID (U	JNII: 65R938	S4DV)						
CAPRYLYL GLYCOL (U	NII: 00YIU54	38U)						
1,2-HEXANEDIOL (UNI	I: TR046Y3K	1G)						
Packaging								
# Item Code	Packa	ge Description	Marketing	g Star	t Date	Marke	ting E	nd Date
1 NDC:86127-002-02	1 in 1 CAR	TON						
1	150 mL in	1 BOTTLE, PLASTIC						
Marketing In	format	ion						
Marketing Category	Applica	Application Number or Monograph Citation		Marketing Start Date		art	Marketing End Date	
UNAPPROVED DRUG OTHER				01/01/2	2022			

Labeler - Nextmune AB (352950223)

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

Establishment

Name	Address	ID/FEI	Business Operations
Medichem SA		464043381	API MANUFACTURE