CLX DERM- chlorhexidine gluconate shampoo 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™

ClxDerm™ 4% chlohexidine digluconate antiseptic shampoofor dogs and cats

Warning: Keep out of reach of children.

Properties:

ClxDerm™ 4% chlohexidine digluconate antiseptic shampoo designed for cleansing the skin of dogs and cats. Chlorhexidine, the active ingredient in ClxDerm™ shampoo 4%, has been proven effective against a broad-spectrum of micro-organisms sensitive to chlorhexidine. The use of ClxDerm™ 4% chlohexidine digluconate antiseptic shampoo will aid in the management of skin infections, supporting a healthy skin barrier.

Directions for use: Wet your pet with warm water and apply shampoo. Massage into wet haircoat. Allow to remain on haircoat for 5-10 minutes before rinsing thoroughly with clean water. Repeat as needed. To improve skin condition, shampoo 1 to 2 times per week in a 1 to 2 week period, or as directed by your veterinarian. To maintain healthy skin, shampoo at least once per month or as directed by your veterinarian.

Precautionary statements:

For external use on dogs and cats only. May cause skin or eye irritation. Avoid getting shampoo 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. If an animal has an adverse reaction to treatment, discontinue use and contact your veterinarian.

Storage: Store at room temperature. Do not freeze.

Composition:

Active ingredient(s):

Chlorhexidine digluconate 4%.

Inactive ingredient(s): deionized water, fragrance, glycerin, hydroxypropyl guar, isodecyl alcohol ethoxylate, lanolin ethoxylated, lauramine oxide, myristamine oxide propylene glycol, Tris-EDTA.

Indications:

For use on dogs and cats only to maintain healthy skin and hair and to enhance hygiene. Aids in the management of skin infections associated with micro-organisms that are sensitive to chlorhexidine.

www.icfpet.com

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

Distributor:

Nextmune US, LLC 2801 S. 35th St.,

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

made

in **Spain**

PRINCIPAL DISPLAY PANEL - 250 ml Bottle Carton

CLXDerm™

4% chlohexidine digluconate

Antiseptic shampoo for dogs and cats

Developed in Italy

iCF™ Evolution of Knowledge

8.45 fl. oz.(250 ml)



IB0432/01

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In nextmune

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

chlohexidine digluconate Antiseptic shampoo

for dogs and cats





Developed in Italy

8.45 fl. oz.(250 ml)

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Inactive ingredient(s): deionized water, fragrance, glycerin, hydroxypropyl guar, isodecyl alcohol ethoxylate, lanolin ethoxylated, lauramine oxide, myristamine oxide propylene glycol, Tris-EDTA.

Indications: For use on dogs and cats only to maintain healthy skin and hair and to enhance hygiene. Aids in the management of skin infections associated with micro-organisms that are sensitive to chlorhexidine.



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CLX DERM

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:86127-001

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE -	CHLORHEXIDINE	40 mg

CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDIN UNII: R4KO0DY52L)

CHLORHEXIDINE GLUCONATE

in 1 mL

Inactive Ingredients		
Ingredient Name	Strength	
water (UNII: 059QF0KO0R)		
glycerin (UNII: PDC6A3C0OX)		
propylene glycol (UNII: 6DC9Q167V3)		
GUARAPROLOSE (3500 MPA.S AT 1%) (UNII: 3A1I7376TC)		
isodecyl alcohol (UNII: 3160X491M7)		
PEG-75 Lanolin (UNII: 091790X7TB)		
TROMETHAMINE (UNII: 023C2WHX2V)		
EDETATE SODIUM (UNII: MP1J8420LU)		
MYRISTAMINE OXIDE (UNII: J086PM3RRT)		
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86127-001-01	1 in 1 CARTON		
1		250 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/2021	

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

Revised: 1/2022 Nextmune AB