STOMODINE F- chlorhexidine gluconate gel 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.

Stomodine™ F

Stomodine™ *F* Chlorhexidine digluconate plaque prevention gel for dogs and cats **Active ingredient(s):** chlorhexidine digluconate 0.2%.

Inactive ingredient(s): cetylpyridinium chloride monohydrate, deionized water, EDTA, ethylhexylglycerin, erythritol, glycerin, hydroxypropyl guar, phytosphingosine, polysorbate 20, preservative (phenoxyethanol), sorbitol, Tris.

Indications: To slow the formation of dental plaque and reduce bad breath. Promotes good oral hygiene.

Directions for use: Between meals, apply the gel between the lips and gums using the special applicator, and lightly message. Apply 1-2 times a day for 15-20 days following your veterinarian's recommendations. Can be used following tooth scaling or dental extractions.

Precautionary statements: For oral use in dogs and cats only. 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. Use before the expiration date provided on the tube.

Warning: Keep out of reach of children.

Look at videos







www.icfpet.com

Distributor:

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

Made in **Spain**

The amount dispensed is based on the following table:

Application Table

For Cats weighing	For Dogs weighing	Length (line of gel)(inches)	
All sizes	≤ 11 lb	0.39	
	11 to 33 lb	0.78	
	33 to 72 lb	1.18	
	> 72 lb	1.54	

PRINCIPAL DISPLAY PANEL - 30 ml Tube Carton

Stomodine[™] F Chlorhexidine digluconate plaque prevention gel for dogs and cats

Developed in Italy

1.01 fl. oz. (30 ml)



STOMODINE F

chlorhexidine gluconate gel

Product Information

Product Type OTC ANIMAL DRUG Item Code (Source) NDC:86127-010

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII: R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	2 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
CETYLPYRIDINIUM CHLORIDE (UNII: D9OM4SK49P)				
WATER (UNII: 059QF0KO0R)				
EDETIC ACID (UNII: 9G34HU7RV0)				
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)				
ERYTHRITOL (UNII: RA96B954X6)				
GLYCERIN (UNII: PDC6A3C0OX)				
PHYTOSPHINGOSINE (UNII: GIN46U9Q2Q)				
POLYSORBATE 20 (UNII: 7T1F30V5YH)				

PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SORBITOL (UNII: 506T60A25R)	
TROMETHAMINE (UNII: 023C2WHX2V)	
GUARAPROLOSE (3500 MPA.S AT 1%) (UNII: 3A1I7376TC)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:86127-010-06	1 in 1 CARTON			
1		30 mL in 1 TUBE			

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