NEUTRA MAXX 5000- sodium fluoride gel
Massco Dental A Division of Dunagin Pharmaceuticals

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.

ACTIVE INGREDIENTS

ACTIVE INGREDIENT	PURPOSE
SODIUM FLUORIDE (NaF) 1.1% (w/v)	ANTICAVITY

INACTIVE INGREDIENTS

DEIONIZED WATER, XYLITOL, POTASSIUM NITRATE, SODIUM CARBOXYMETHYLCELLOSE, GLYCERIN, FLAVORING,SODIUM SACCHARIN, SODIUM PHOSPHATE .

USE

USE: AIDS IN THE PREVENTION OF DENTAL DECAY IN PEDIATRIC PATIENTS AND ADULTS

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN. IF MORE SOLUTION IS ACCIDENTALLY SWALLOWED THAN USED FOR BRUSHING, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

DIRECTIONS: (UNLESS INSTRUCTED OTHERWISE BY YOUR DENTAL PROFESSIONAL)

ADULTS AND CHILDREN 6 YEARS AND OLDER: USE ONCE A DAY AFTER BRUSHING TEETH WITH TOOTHPASTE. AFTER RINSING, APPLY THIN RIBBON OF GEL TO TEETH WITH TOOTHBRUSH OR MOUTH TRAYS FOR AT LEASE ONE MINUTE. BEFORE BEDTIME IS BEST. ADULTS SHOULD EXPECTORATE AFTER USE. CHILDREN AGES 6-16 SHOULD EXPECTORATE GEL AND RINSE MOUTH THOROUGHLY. DO NOT EAT OR DRINK FOR 30 MINUTES AFTER USE.

WARNINGS

WHEN USING THIS PRODUCT DO NOT SWALLOW UNLESS TOLD TO DO SO BY A DENTIST OR PHYSICIAN.

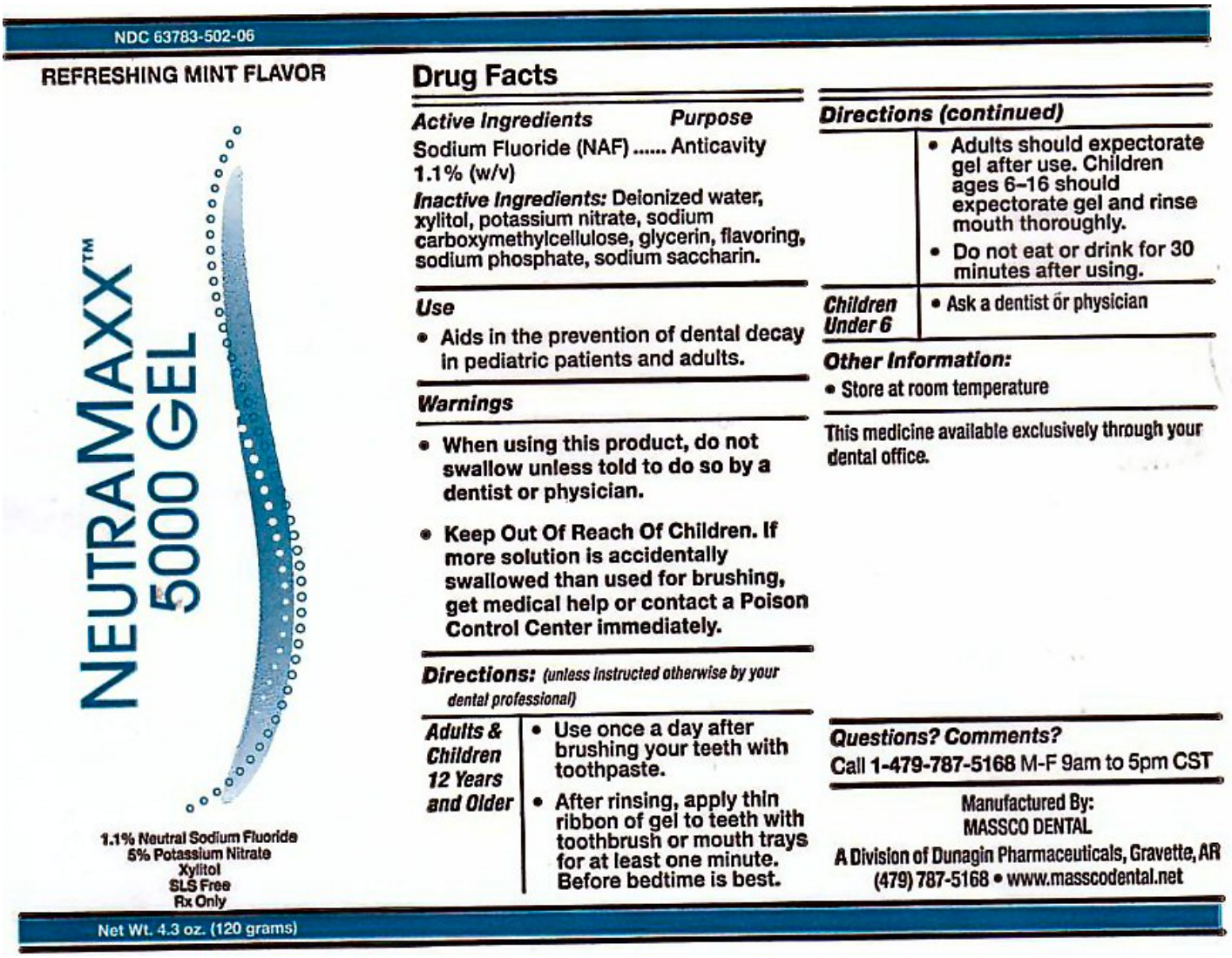
PACKAGE LABEL

NEUTRA MAXX 5000PPM GEL REFRESHING MINT FLAVOR

THE MAXIMUM AMOUNT OF FLUORIDE AVAILABLE 1.1% SODIUM FLUORIDE 5% POTASSIUM NITRATE XYLITOL SLS FREE Rx ONLY. NET WT 4.3 oz (120 g)

MANUFACTURED BY MASSCO DENTAL A DIVISION OF DUNAGIN PHARMACEUTICALS GRAVETTE, AR 72736 THE MEDICINE AVAILABLE EXCLUSIVELY THROUGH YOUR DENTAL OFFICE.

OTHER INFORMATION: STORE AT ROOM TEMPERATURE QUESTION? COMMENTS? CALL 1-479-787-5168 M-F 9AM TO 5PM CST



NEUTRA MAXX 5000

sodium fluoride gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63783-504
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	1.428 g in 120 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
POTASSIUM NITRATE (UNII: RU45X2JN0Z)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE (UNII: SE337SVY37)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MINT (Mint)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63783-504-06	120 g in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/1989	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/01/1989	

Labeler - Massco Dental A Division of Dunagin Pharmaceuticals (008081858)

Registrant - Massco Dental A Division of Dunagin Pharmaceuticals (008081858)

Establishment

Name	Address	ID/FEI	Business Operations
Massco Dental A Division of Dunagin Pharmaceuticals		008081858	manufacture(63783-504)