FLUORITAB CHEWABLE CHERRY- sodium fluoride tablet, chewable Fluoritab Corporation

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.

CONTAINS: 2.2 MG SODIUM FLUORIDE

EACH TABLET CONTAINS 1 MG FLUORIDE

PPM FLUORIDE IONDAILY DOSAGE

IN DRINKING WATERAGE 6 MO. – 3 YRS.AGE 3-6 YRS.AGE 6-16 YRS.

LESS THAN 0.3 PPM0.25 MG 0.50 MG1 MG

0.3 TO 0.6 PPMNONE 0.25 MG 0.50 MG

OVER 0.6 PPMNONENONE

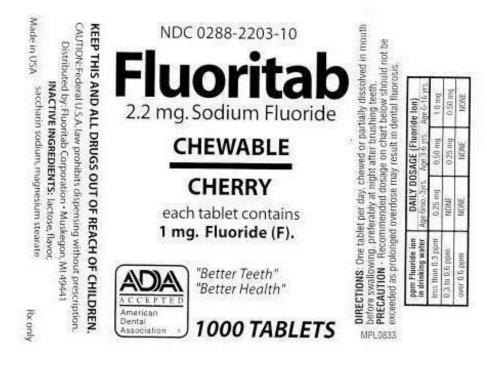
KEEP OUT OF REACH OF CHILDREN.

CAUTION: FEDERAL (U.S.A.) LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.

DIRECTIONS: ONE TABLET PER DAY, CHEWED OR PARTIALLY DISSOLVED IN MOUTH BEFORE SWALLOWING, PREFERABLY AT NIGHT AFTER BRUSHING TEETH.

INACTIVE INGREDIENTS: LACTOSE, FLAVOR, SACCHARIN SODIUM, MAGNESIUM STEARATE

PRECAUTION -RECOMMEND DOSAGE ON CHART BELOW SHOULD NOT BE EXCEEDED AS PROLONGED OVERDOSE MAY RESULT IN DENTAL FLUOROSIS.



FLUORITAB CHEWABLE CHERRY

sodium fluoride tablet, chewable

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0288-2203
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80 VPU408O)	FLUORIDE ION	1 mg		

Inactive Ingredients		
Ingredient Name	Strength	
LACTOSE (UNII: J2B2A4N98G)		
SACCHARIN SO DIUM ANHYDRO US (UNII: I4807BK602)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		

Product Characteristics				
Color	white	Score	no score	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code		
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0288-2203-01	100 in 1 BOTTLE		
2	NDC:0288-2203-10	1000 in 1 BOTTLE		
3	NDC:0288-2203-02	5000 in 1 BOTTLE		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		01/09/2011		

Labeler - Fluoritab Corporation (005376702)

Registrant - Fluoritab Corporation (005376702)

Establishment				
Name	Address	ID/FEI	Business Operations	
Medical Products Laboratories		002290302	manufacture(0288-2203)	

Revised: 10/2012 Fluoritab Corporation