

FLUORIDE DROPS - sodium fluoride liquid
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.

FLUORITAB FLUORIDE DROPS 1 fluid ounce size

CONTAINS: SODIUM FLUORIDE IN AN AQUEOUS VEHICLE WITH PRESERVATIVE.
EACH 8 DROPS EQUIVALENT TO 1 MG. F. (FROM 2.2 MG SODIUM FLUORIDE)

PPM FLUORIDE ION		DAILY DOSAGE	
IN DRINKING WATER	AGE 6 MO. – 3 YRS.	AGE 3-6 YRS.	AGE 6-16 YRS.
LESS THAN 0.3 PPM	2 DROPS	4 DROPS	8 DROPS
0.3 TO 0.6 PPM	NONE	2 DROPS	4 DROPS
OVER 0.6 PPM	NONE	NONE	NONE

KEEP OUT OF REACH OF CHILDREN.

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

CONTRAINDICATIONS: PATIENTS WITH MEDICAL CONDITION OF DENTAL FLUOROSIS.

PRODUCT CATEGORY: DENTAL CARIES PROPHYLACTIC, NUTRITIONAL SUPPLEMENT (MINERAL)

ACTIONS AND INDICATIONS: FLUORITAB DROPS CONTAINING SODIUM FLUORIDE (SYSTEMIC) IS INDICATED AS A DIETARY SUPPLEMENT FOR PREVENTION OF DENTAL CARIES IN CHILDREN IN THE AREAS WHERE THE LEVEL OF FLUORIDE IN DRINKING WATER IS INADEQUATE.

INACTIVE INGREDIENTS: WATER, PRESERVATIVE.

EXCESSIVE DOSES OF SODIUM FLUORIDE MAY RESULT IN FLUOROSIS OF TEETH IF TAKEN DURING FORMATION YEARS.

FLUORITAB FLUORIDE DROPS
DISTRIBUTED BY:
FLUORITAB CORPORATION
"BETTER TEETH - BETTER HEALTH"
MUSKEGON, MI 49441

MADE IN U.S.A.

NDC 0288-5523-23

KEEP OUT OF REACH OF CHILDREN

FLUORIDE Fluoritab drops 1 fl. oz

Contains: Sodium Fluoride in an aqueous vehicle with preservative.
Each 8 drops equivalent to 1mg. F. (From 2.2mg Sodium Fluoride).

M1056

	DAILY DOSAGE		
ppm Fluoride ion in drinking water	Age 6 mo.-3yrs.	Age 3-6 yrs.	Age 6-16 yrs.
less than 0.3 ppm	2 drops	4 drops	8 drops
0.3 to 0.6 ppm	NONE	2 drops	4 drops
over 0.6 ppm	NONE	NONE	NONE

CAUTION: Federal law prohibits dispensing without prescription.

Distributed By:
Fluorid Corporation
"Better Teeth - Better Health"
Muskegon, MI 49441

FLUORIDE Fluoritab drops

Product Category: Dental caries prophylactic, nutritional supplement (mineral)

Actions and Indications: Fluoritab drops containing sodium fluoride (systemic) is indicated as a dietary supplement for prevention of dental caries in children in the areas where the level of fluoride in drinking water is inadequate.

Contraindications: Patients with medical condition of dental fluorosis.

Cautions: Federal (U.S.A.) law prohibits dispensing without prescription. Excessive doses of sodium fluoride may result in fluorosis of teeth if taken during tooth formation years.

Contents:

- Drops:** 1.0 mg. Fluoride ion per eight Fluoritab drops.
- Dosage:** See product container for dosage information.
- Direction:** Dispense prescribed dosage from the bottle using supplied dropper or refer to the directions on the label.

"The ADA Council on Scientific Affairs' Acceptance of Fluoritab drops, is based on its finding that the product is effective in helping to prevent and reduce tooth decay, when used as directed."

Distributed By:
Fluoritab Corporation
"Better Teeth - Better Health"
Muskegon, MI 49441

MADE IN U.S.A.

M1061

FLUORIDE DROPS

sodium fluoride liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0288-5523
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0288-5523-01	30 mL in 1 BOTTLE, DROPPER		

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, analysis

Establishment

Name	Address	ID/FEI	Business Operations
Fluoritab Corporation		005376702	label

Revised: 5/2011

Fluoritab Corporation