TOPEX NEUTRAL FLUORIDE FOAM- sodium fluoride aerosol, foam
Dentsply LLC. Professional Division Trading as "Sultan Healthcare"

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.

Topex Neutral Fluoride Foam

INDICATIONS AND USAGE

Topex® Fluoride Foams are indicated for topical application to teeth to aid in the prevention of dental caries.

The non-acidic nature of Neutral pH (NaF) is recommended for patients with ceramic or composite restorations.

DOSAGE AND ADMINSTRATION

1. Remove cap from can. If this is the first time using can, break the protective shipping tab by gently lifting up the trigger.

2. Shake can thoroughly for at least 10 seconds before each use.

3. Completely invert can and slowly depress trigger to dispense foam into a fluoride tray

4. Air dry teeth thoroughly and insert tray into patient’s mouth. Have patient close into the tray and use a slight chewing motion to ensure interproximal coverage.

5. Leave tray in contact with teeth between 1-4 minutes. Use a saliva ejector during treatment to minimize ingestion of product

6. Remove tray after elapsed time and have patient expectorate. Instruct patient to refrain from drinking, eating, or rinsing for 30 minutes after treatment.

Treatment frequency should not exceed 4 treatments per year.

DOSAGE FORMS AND STRENGTHS

APF topical Foam contains 2.73% sodium fluoride (1.23% fluoride ion).

NaF topical gel contains 2.0% sodium fluoride (0.9% fluoride ion).

CONTRAINDICATIONS

Hypersensitivity to fluoride. Do not use if patient has a known allergy to fluoride or any of the other ingredients in this product.

WARNINGS AND PRECAUTIONS

Do not swallow. Harmful if swallowed.

Keep out of reach of children.
This product is not intended for home or unsupervised consumer use.
Contents under pressure. Do not puncture or incinerate canister.
Safety and effectiveness below age 3 have not been established. There have been no long-term animal studies with this product to evaluate carcinogenic, mutagenic, or impairment of fertility potential.
Laboratory studies have indicated that repeated use of APF may dull porcelain, composite restorations and sealants.

ADVERSE REACTIONS

Developing teeth of children under age 6 may become permanently discolored if excessive amounts are repeatedly swallowed. The following adverse reactions are possible in individuals hypersensitive to fluoride: eczema, atopic dermatitis, urticarial, gastric distress, headache, and weakness.

OVERDOSAGE

If treatment dose is swallowed (less than 100 mg F ion), administer milk, limewater, or calcium-type antacid. In case of larger doses, use ipecac syrup emetic and immediately seek medical help. Overdose symptoms include nausea, vomiting, diarrhea, and abdominal pain.

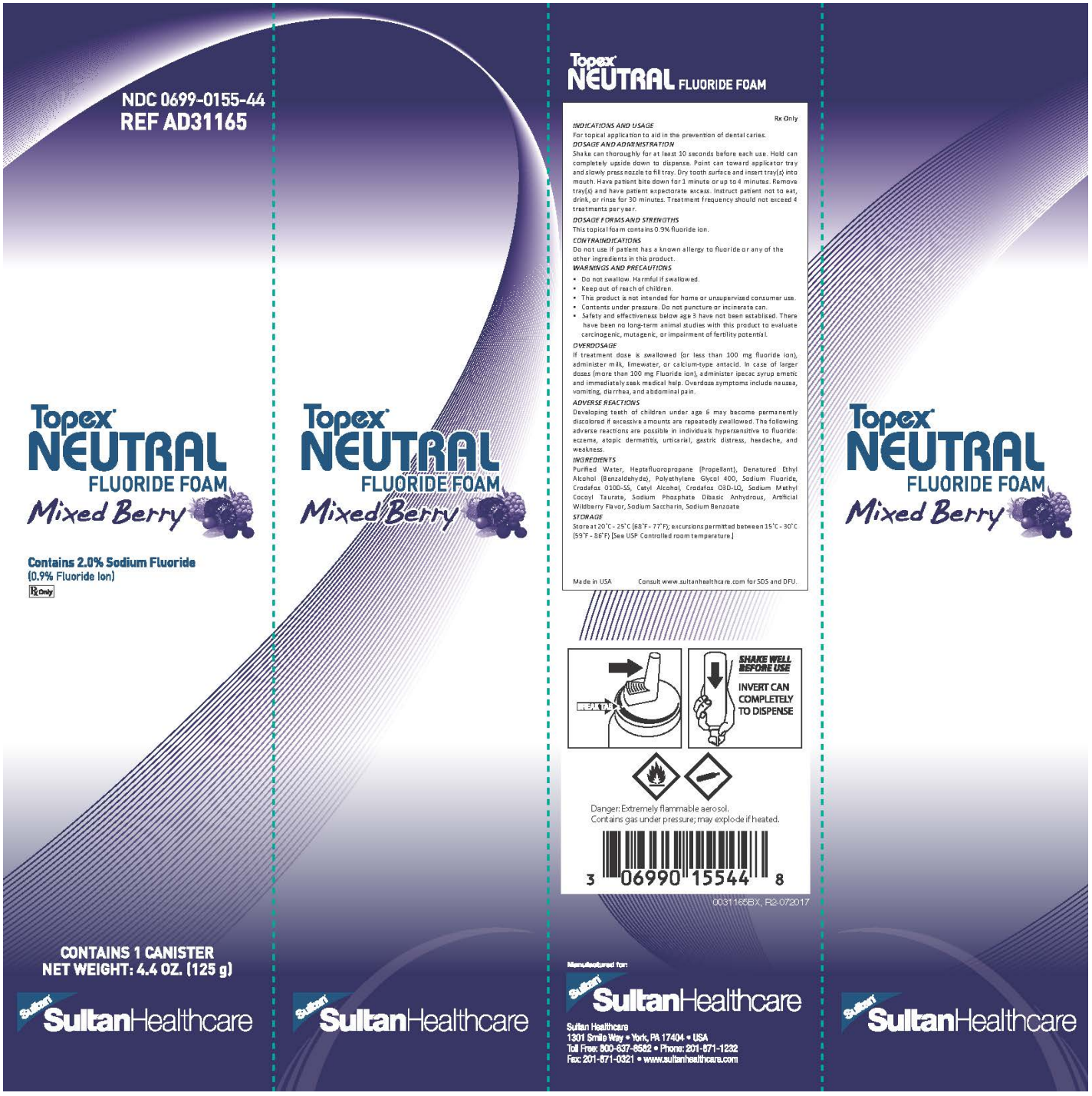
DESCRIPTION

Topex® Fluoride Foams are a family of topical fluoride foam products for professional application in trays. The family consists of APF Foam (1.23% fluoride ion at a pH between 3.0-4.5) and Neutral pH Foam (0.9% fluoride ion at a pH between 6.5 -7.5). Topex® Foam Fluoride products do not contain chlorofluorocarbon propellants.

STORAGE AND HANDLING

Store at 20°C - 25°C (68° - 77°F); excursions permitted between 15°C - 30°C (59° - 86°F) [See USP Controlled room temperature.]

PRINCIPAL DISPLAY PANEL - Mixed Berry



TOPEX NEUTRAL FLUORIDE FOAM

sodium fluoride aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0699-0155
Route of Administration	DENTAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.02 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
WATER (UNII: 059QF0KO0R)	
BENZALDEHYDE (UNII: TA269SD04T)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
APAFLURANE (UNII: R40P36GDK6)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
DIETHANOLAMINE OLETH-10 PHOSPHATE (UNII: 55HSP2Q1LM)	
DIETHANOLAMINE OLETH-3 PHOSPHATE (UNII: Y67NX5905E)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor	BERRY (Mixed Berry)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-0155-44	1 in 1 CARTON	01/01/1997	
1		125 g in 1 CANISTER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		01/01/1997	

Labeler - Dentsply LLC. Professional Division Trading as "Sultan Healthcare" (167087753)

Establishment

Name	Address	ID/FEI	Business Operations
Sciarra Laboratories, Inc.		824900369	MANUFACTURE(0699-0155)