

HELLO UNICORN SPLASH- sodium fluoride mouthwash
Accupac LLC

Hello Unicorn Splash
unicorn splash anticavity fluoride rinse

Drug Facts

Active ingredient

Sodium fluoride 0.05% (0.02% w/v fluoride ion)

Purpose

Anticavity

Use

aids in the prevention of dental cavities.

Warnings

Keep out of reach of children.

If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 6 years of age and older:

Use once a day after brushing your teeth with a toothpaste.

Vigorously swish 10 mL (2 teaspoons) of rinse between your teeth for 1 minute and then spit out.

Do not swallow the rinse.

Do not eat or drink for 30 minutes after rinsing.

Instruct children under 12 years of age in good rinsing habits (to minimize swallowing).

Supervise children as necessary until capable of using without supervision.

Children under 6 years of age: consult dentist or doctor.

Other information

Store at room temperature

Do not use if printed band around cap is broken or missing.

Inactive ingredients

purified water, vegetable glycerin, xylitol, sodium phosphate monobasic, flavor, poloxamer 407, potassium citrate, phosphoric acid.

Questions?

1-855-444-3556

Dist. by Hello Products LLC

Montclair, NJ 07042

PRINCIPAL DISPLAY PANEL - 520 mL Bottle Label

hello

unicorn splash

anticavity fluoride rinse

bubble gum

natural flavor

prevents cavities • no alcohol

strengthens teeth

17.6 FL OZ (1.1 PT) 520 mL

PS0086273

IMPORTANT:

Read directions for proper use.

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IMPORTANT:
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your swish come true.
a magical anticavity rinse that tastes like rainbows and sunshine (aka bubble gum). thoughtfully formulated with fluoride to help prevent cavities and strengthen teeth. bonus, not tested on animals, real or imaginary.

vegan. no alcohol. no dyes.
no artificial sweeteners. no artificial flavors.
no SLS. no spicy mint. no brainer.

Drug Facts	Drug Facts (continued)
Active ingredient Purpose Sodium Fluoride 0.045% (0.02% w/v fluoride ion).....Anticavity	Directions Adults and children 6 years of age and older: • use once a day after brushing your teeth with a toothpaste • vigorously swish 10 mL (2 teaspoonfuls) of rinse between your teeth for 1 minute and then spit out • do not swallow the rinse • do not eat or drink for 30 minutes after rinsing • instruct children under 12 years of age in good rinsing habits (to minimize swallowing) • supervise children as necessary until capable of using without supervision Children under 6 years of age: consult a dentist or doctor
Use aids in the prevention of dental cavities.	Other information • store at room temperature • do not use if printed band around cap is broken or missing
Warnings Keep out of reach of children. If more than used for rinsing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	Inactive ingredients water, glycerin, xylitol, sodium phosphate, poloxamer 407, flavor, phosphoric acid, potassium citrate.
for your protection, this cap is sealed with a printed band.	Questions? 1-855-444-3556

swish happy™

contains no ethyl alcohol

this bottle is made from 100% post-consumer recycled plastic*
*excludes label & cap

not tested on animals.

Dist. by Colgate-Palmolive Co.
New York, NY 10022
855-HI-HELLO
www.helloproducts.com

PS0086391

HELLO UNICORN SPLASH

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:44038-0687
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.02 g in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS (UNII: KH7I04HPUU)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
XYLITOL (UNII: VCQ006KQ1E)	
POLOXAMER 407 (UNII: TUF2IWW3M2)	
PHOSPHORIC ACID (UNII: E4GA8884NN)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44038-0687-1	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2023	11/30/2027
2	NDC:44038-0687-2	520 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/01/2026	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M021	07/01/2023	

Labeler - Accupac LLC (071609663)

Registrant - Accupac LLC (061595175)

Establishment			
Name	Address	ID/FEI	Business Operations
Accupac LLC		061595175	manufacture(44038-0687)