

FLUORIDE MOUTHWASH SOFT MINT- sodium fluoride mouthwash
Swiss Shine Beauty AG

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Fluoride Mouthwash Soft Mint

Active Ingredients

Sodium fluoride 0.05% (0.02% w/v fluoride ion) Purpose: Anticavity

Use

- Aids in the prevention of dental cavities.

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.

Do not swallow the rinse

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

Directions

- Shake well before use.
- Adults and children 6 years of age and older: Use once a day after brushing your teeth with a toothpaste.
- Vigorously swish 10 milliliters 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.

- You may report serious side effects to: Swiss Shine Beauty, Inc

651 N. Broad St., Middletown, DE 19709

- Tamper evident: Do not use if safety seal is broken or missing.

Inactive ingredients

water, glycerin, propylene glycol, xylitol, peg-40 hydrogenated castor oil, sodium citrate, flavor, zinc lactate, poloxamer 407, chlorhexidine digluconate, citric acid, hydrochloric acid, oligopeptide-104, sodium hydroxide

vVARDIS

SWITZERLAND

WEISSBAD

FRESH AND PROTECT

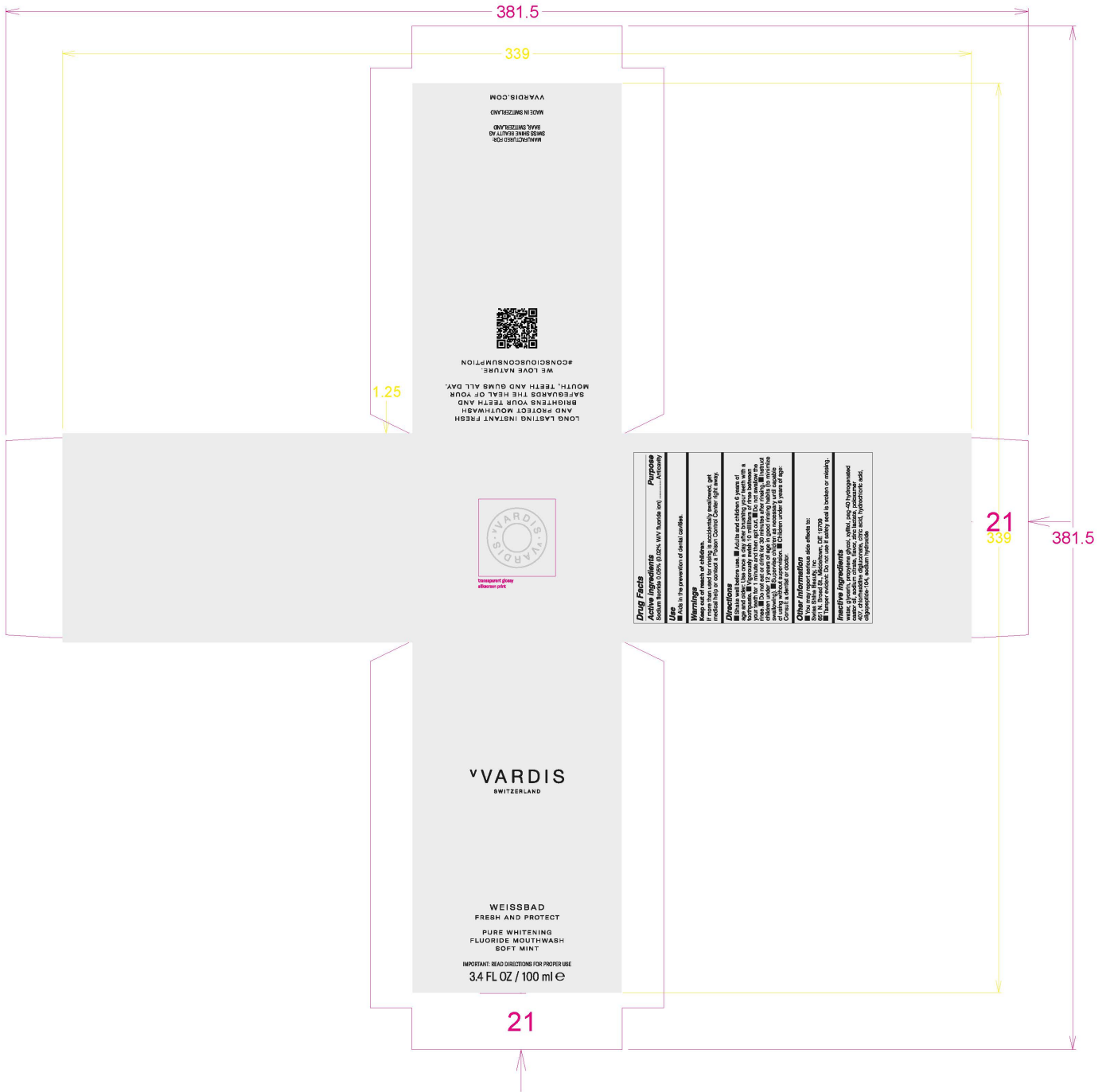
PURE WHITENING

FLUORIDE MOUTHWASH

SOFT MINT

IMPORTANT: READ DIRECTIONS FOR PROPER USE

3.4 FL OZ / 100 ml e



FLUORIDE MOUTHWASH SOFT MINT

sodium fluoride mouthwash

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79763-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	SODIUM FLUORIDE	0.05 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
ZINC LACTATE (UNII: 2GXR25858Y)	
POLOXAMER 407 (UNII: TUF2IVW3M2)	
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0KO0R)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79763-002-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/21/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/21/2020	

Labeler - Swiss Shine Beauty AG (480422958)**Establishment**

Name	Address	ID/FEI	Business Operations
System Kosmetik Produktionsgesellschaft fur kosmetische Erzeugnisse mbH		328825757	manufacture(79763-002)

Establishment

Name	Address	ID/FEI	Business Operations
Marvinpac SA		482060329	pack(79763-002)

Revised: 8/2020

Swiss Shine Beauty AG