

**VVARDIS SET STRONG MINT- sodium monofluorophosphate, sodium fluoride  
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.*

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**VVARDIS SET STRONG MINT**

Mouthwash

**Active ingredients**

Sodium fluoride 0.05% (0.02% W/V fluoride ion) Purpose Anticavity

Toothpaste

**Active Ingredients**

Sodium monofluorophosphate 0.88% (0.115% W/V fluoride ion) Purpose Anticavity

**Use**

Aids in the prevention of dental cavities.

**Keep out of reach of children.**

Supervise children as necessary until capable of using without supervision.

**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.

**Warnings** Keep out of reach of children under 6 years of age. If more than used for brushing 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.

**Directions**

Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a dentist or doctor.

Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing)

Supervise children as necessary until capable of using without supervision.

Children under 2 years of age: consult a dentist or doctor.

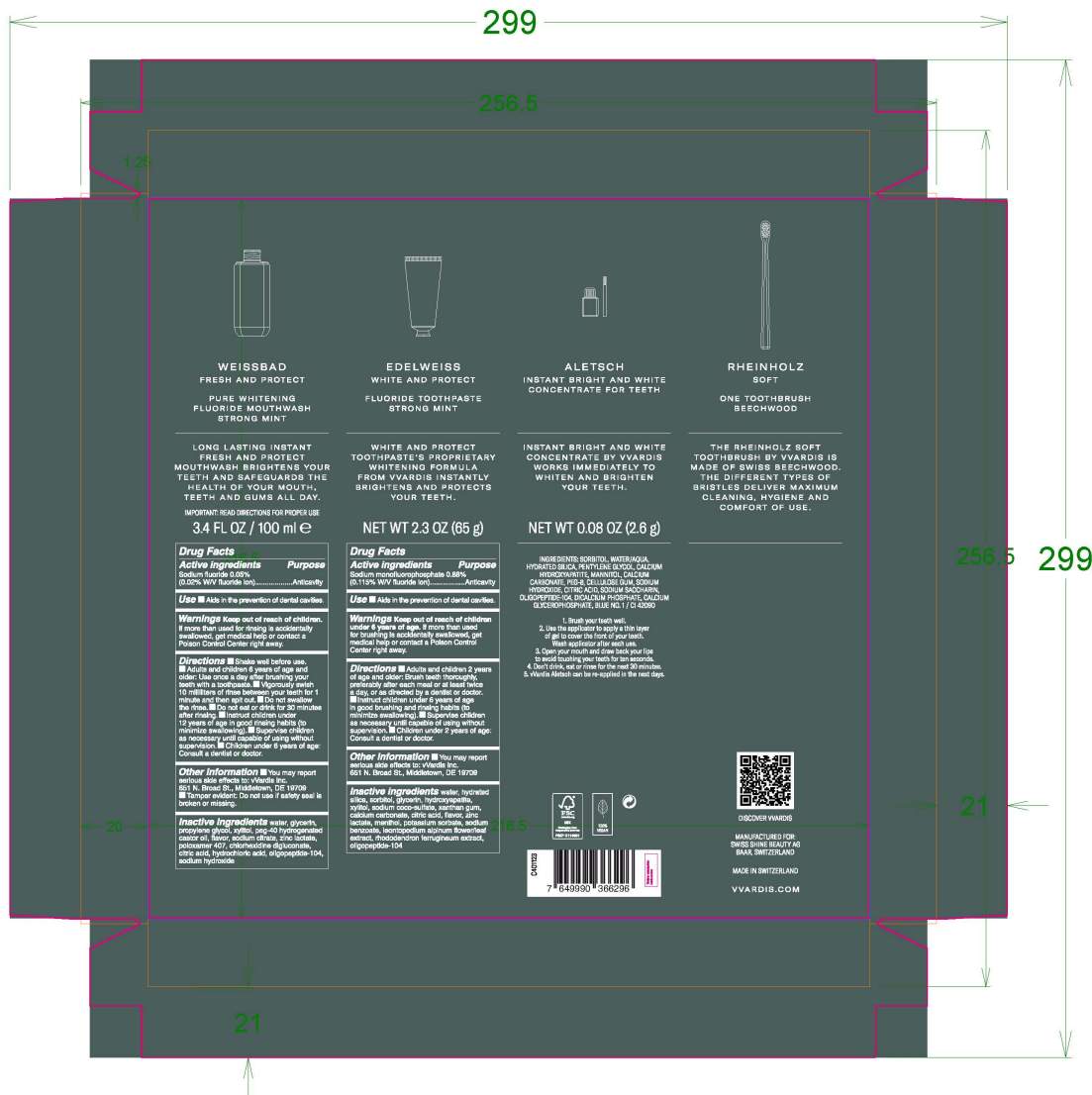
# Inactive Ingredients

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

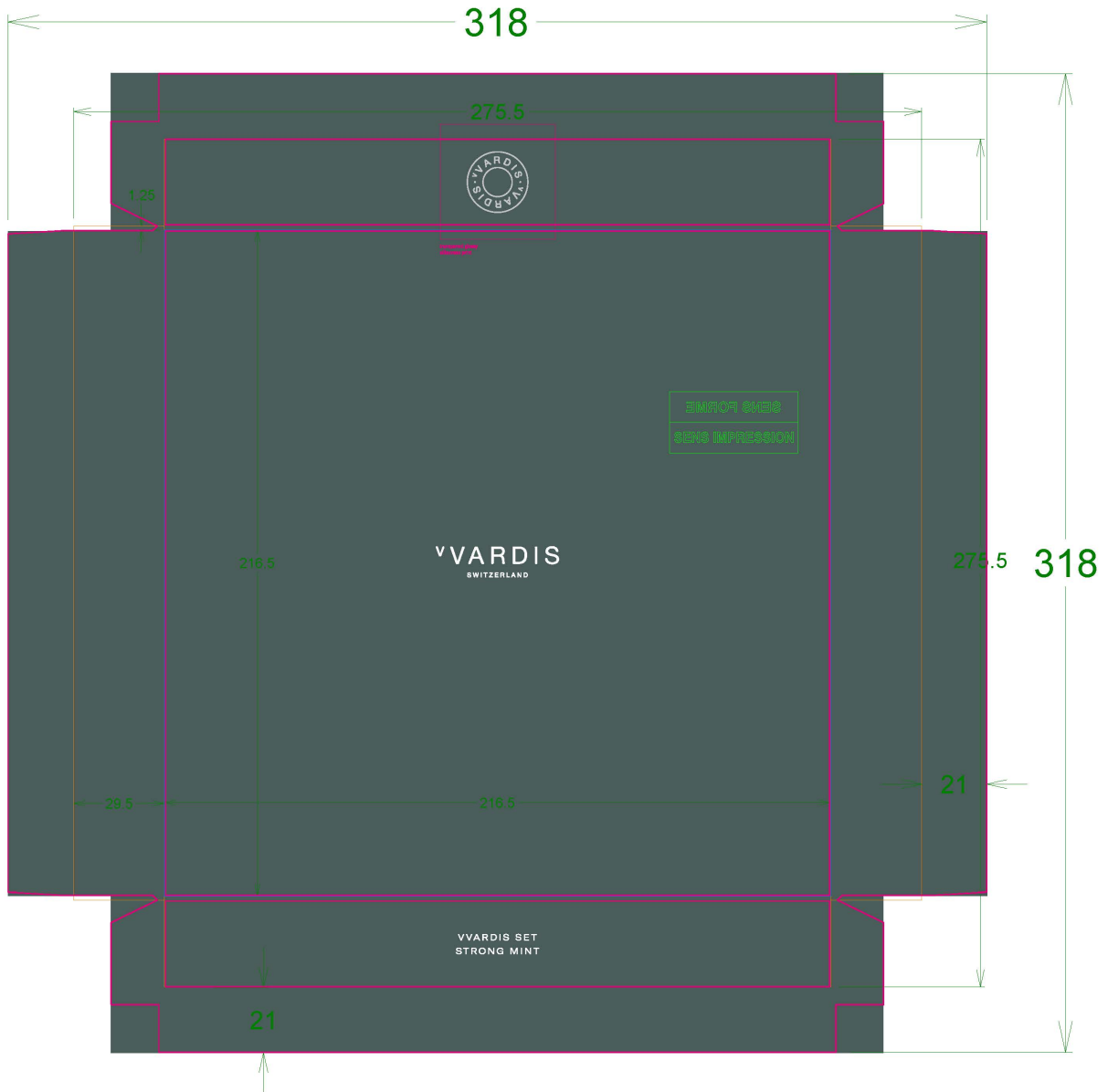
**Inactive Ingredients** water, hydrated silica, sorbitol, glycerin, hydroxyapatite, xylitol, sodium coco-sulfate, xanthan gum, calcium carbonate, citric acid, flavor, zinc lactate, menthol, potassium sorbate, sodium benzoate, leontopodium alpinum flower/leaf extract, rhododendron ferrugineum extract, oligopeptide-104

VVardis Set Strong Mint

US  
V1



US



## VVARDIS SET STRONG MINT

sodium monofluorophosphate, sodium fluoride kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:79763-008
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79763-008-01	1 in 1 KIT	10/14/2020	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	100 mL in 100
Part 2	1 TUBE	65 g in 65
Part 3	1 BOTTLE, WTH APPLICATOR	2.6 g in 100

## Part 1 of 3

### PURE WHITENING FLUORIDE MOUTHWASH STRONG MINT

sodium fluoride liquid

## Product Information

Route of Administration DENTAL

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		100 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	10/15/2020	

## Part 2 of 3

### FLUORIDE STRONG MINT

sodium monofluorophosphate gel

## Product Information

Route of Administration ORAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM MONOFLUOROPHOSPHATE</b> (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.88 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM COCO-SULFATE</b> (UNII: 3599J29ANH)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>ZINC LACTATE</b> (UNII: 2GXR25858Y)	
<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	
<b>RHODODENDRON FERRUGINEUM WHOLE</b> (UNII: FO6B1S7BZU)	
<b>LEONTOPODIUM ALPINUM FLOWERING TOP</b> (UNII: QQC1AK06RK)	
<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y6O7T4G8P9)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>XYLITOL</b> (UNII: VCQ006KQ1E)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		65 g in 1 TUBE; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	10/15/2020	

## Part 3 of 3

### INSTANT BRIGHT AND WHITE CONCENTRATE FOR TEETH

other oral hygiene products gel

## Product Information

Route of Administration DENTAL

## Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	<b>SORBITOL</b> (UNII: 506T60A25R)	
INGR	<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
INGR	<b>WATER</b> (UNII: 059QF0K00R)	
INGR	<b>MANNITOL</b> (UNII: 3OWL53L36A)	
INGR	<b>PENTYLENE GLYCOL</b> (UNII: 50C1307PZG)	
INGR	<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
INGR	<b>TRIBASIC CALCIUM PHOSPHATE</b> (UNII: 91D9GV0Z28)	
INGR	<b>CALCIUM CARBONATE</b> (UNII: H0G9379FGK)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2.6 g in 1 BOTTLE, WTH APPLICATOR; Type 1: Convenience Kit of Co-Package		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		10/15/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
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OTC monograph final	part356	10/14/2020	
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**Labeler** - Swiss Shine Beauty AG (480422958)

**Establishment**

Name	Address	ID/FEI	Business Operations
System Kosmetik Produktionsgesellschaft fur kosmetische Erzeugnisse mbH		328825757	manufacture(79763-008)

**Establishment**

Name	Address	ID/FEI	Business Operations
Marvinpac SA		482060329	pack(79763-008)

Revised: 8/2021

Swiss Shine Beauty AG