

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

VVARDIS SET SOFT MINT

Active Ingredients

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

Purpose Anticavity

Active Ingredients

Sodium monofluorophosphate 0.88% (0.115% 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.

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.

Supervise children as necessary until capable of using without supervision.

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

Supervise children as necessary until capable of using without supervision.

Children under 6 years of age: Consult a dentist or doctor.

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, glycerine, 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

Inactive Ingredients

water, hydrated silica, hydrogenated starch hydrolysate, glycerin, hydroxyapatite, xylitol, sodium coco-sulfate, calcium carbonate, flavor, xanthan gum, citric acid, potassium sorbate, sodium benzoate, leontopodium alpinum flower/leaf extract, rhododendron ferrugineum extract, oligopeptide-104, lactic acid.

Other information

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.

WEISSBAD

FRESH AND PROTECT

PURE WHITENING

FLUORIDE MOUTHWASH

SOFT MINT

100 ml e /3.4 FL OZ

EDELWEISS

WHITE AND PROTECT


FLUORIDE TOOTHPASTE

SOFT MINT

NET WT 2.3 OZ (65 g)

PRINT / US

299




WEISSBAD
FRESH AND PROTECT
PURE WHITENING
FLUORIDE MOUTHWASH
SOFT MINT

LONG LASTING INSTANT
FRESH AND PROTECT
MOUTHWASH BRIGHTENS YOUR
TEETH AND SAFEGUARDS THE
HEAL OF YOUR MOUTH, TEETH
AND GUMS ALL DAY.

100 ml e / 3.4 FL OZ

Drug Facts	
Active ingredients	Purpose
Sodium fluoride 0.05% (0.02% WV fluoride ion)	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 Brush 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 15 years of age in good rinsing habits for minimum effectiveness. Supervise children as necessary until capable of using without supervision. Children under 6 years of age: Consult a dentist or doctor.	
Other information You may report serious side effects to: Swiss Swiss Beauty Inc 651 N. Broad St., Middletown, DE 19709. Sample packet: Do not use if safety seal is broken or missing.	
Inactive ingredients water, glycerin, propylene glycol, xylitol, cap-yl hydroxyethyl candel oil, sodium citrate, flavor, zinc lactate, potassium ACI, chlorhexidine digluconate, citric acid, hydrochloric acid, di(isodecyl-10A), sodium hydroxide	




EDELWEISS
WHITE AND PROTECT
FLUORIDE TOOTHPASTE
SOFT MINT

WHITE AND PROTECT
TOOTHPASTE'S PROPRIETARY
WHITENING FORMULA
FROM VVARDIS INSTANTLY
BRIGHTENS AND PROTECTS
YOUR TEETH.

NET WT 2.3 OZ (65 g)

Drug Facts	
Active ingredients	Purpose
Sodium monofluorophosphate 0.88% (0.115% WV fluoride ion)	Anticavity
Use Aids in the prevention of dental cavities.	
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 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 (not rinsing) habits for minimum effectiveness. Supervise children as necessary until capable of using without supervision. Children under 2 years of age: Consult a dentist or doctor.	
Other information You may report serious side effects to: Swiss Swiss Beauty Inc 651 N. Broad St., Middletown, DE 19709	
Inactive ingredients water, hydrated silica, hydrogenated starch hydrolysis, glycerin, hydroxyapatite, xylitol, sodium coo- salate, sodium carbonate, flavor, sorbitol gum, citric acid, potassium acetate, sodium benzoate, sorbitolum adipicum flower/leaf extract, rhododendron ferrugineum extract, di(isodecyl-10A), lactic acid	




ALETSCH
INSTANT BRIGHT AND WHITE
CONCENTRATE FOR TEETH

INSTANT BRIGHT AND WHITE
TOOTHBRUSH BY VVARDIS
WORKS IMMEDIATELY TO
WHITEN AND BRIGHTEN
YOUR TEETH.

NET WT 0.08 OZ (2.6 g)


Drug Facts	
Active ingredients	Purpose
INGREDIENTS: SORBITOL, WATER/ACQUA, HYDROXYETHYL PHTHALATE, CALCIUM HYDROXYAPATITE, MANNITOL, CALCIUM CARBONATE, POLY-ETHYLENE GLYCOL, SODIUM HYDROXIDE, CITRIC ACID, SODIUM SACCHARIN, CHLOROPHTHOLIC SODIUM PHOSPHATE, CALCIUM GLUCONOPHTHALATE, BLUE NO.1 (CI 42000)	
Use Aids in the prevention of dental cavities.	
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 1. Brush your teeth well. 2. Use the application to apply a thin layer of gel to cover the front of your teeth. Wash application after each use. 3. Open your mouth and draw back your lips to avoid brushing your teeth for ten seconds. 4. Don't drink, eat or rinse for the next 30 minutes. 5. While Aletsch can be re-applied in the next days.	



RHEINHOLZ
SOFT
TOOTHBRUSH
BEECHWOOD


THE RHEINHOLZ SOFT
TOOTHBRUSH BY VVARDIS IS
MADE OF SWISS BEECHWOOD.
THE DIFFERENT TYPES OF
BRISTLES DELIVER MAXIMUM
CLEANING, HYGIENE AND
COMFORT OF USE.

WE LOVE NATURE.
#CONSCIOUSCONSUMPTION



MANUFACTURED FOR:
SWISS SWISS BEAUTY AG
BAAR, SWITZERLAND
MADE IN SWITZERLAND
VVARDIS.COM

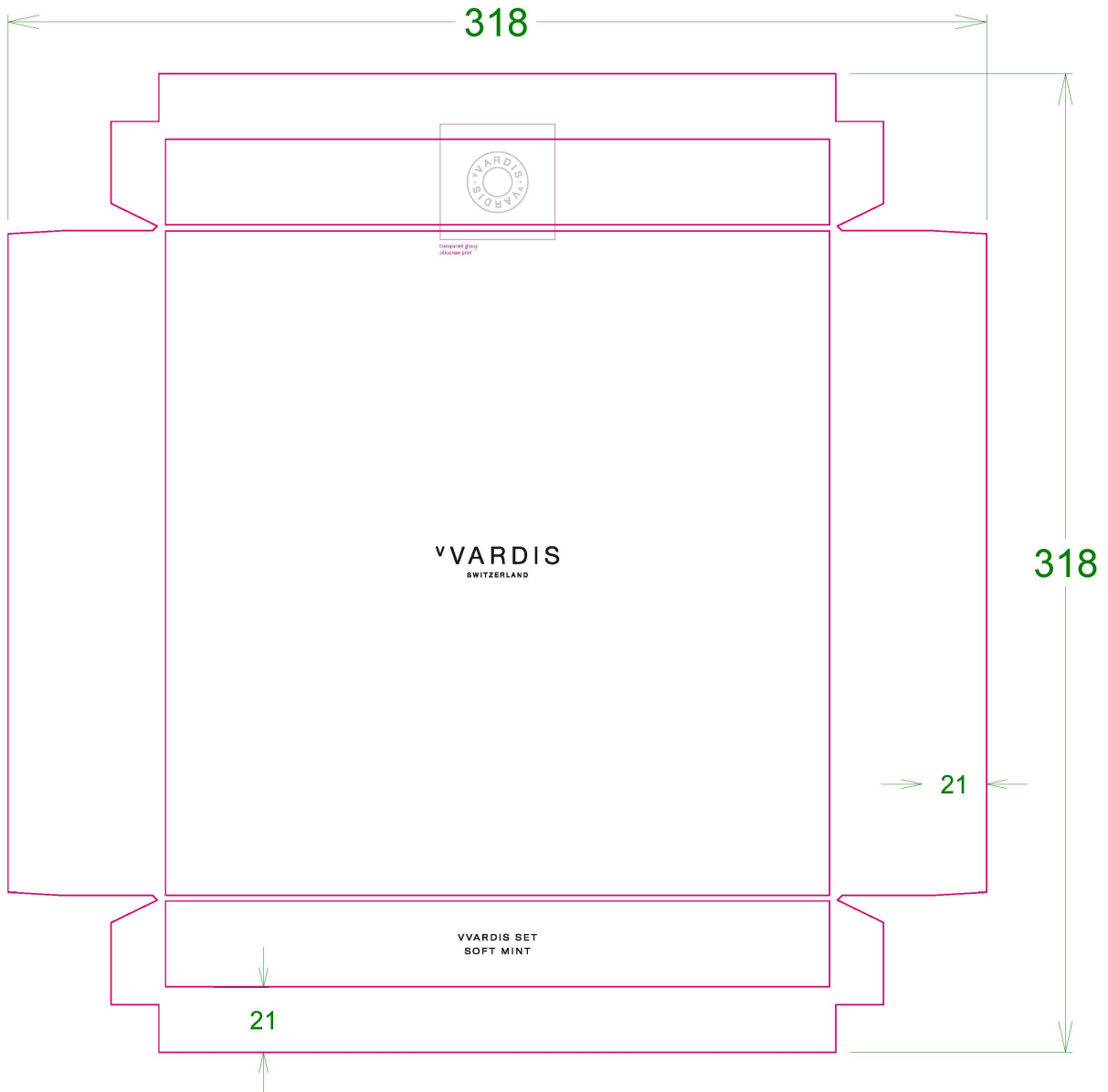
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VWARDIS SET SOFT MINT

sodium fluoride, sodium monofluorophosphate kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79763-004
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79763-004-	1 in 1 KIT; Type 1: Convenience Kit of Co-	07/22/2020	

01	Package	07/22/2020
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Quantity of Parts

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

Part 1 of 3

FLOURIDE MOUTHWASH SOFT MINT

sodium flouride mouthwash

Product Information

Item Code (Source)	NDC:79763-005
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM FLUORIDE (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU4080)	SODIUM FLUORIDE	0.05 g in 100 mL

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79763-	100 mL in 1 BOTTLE; Type 1: Convenience Kit of		

005-01	Co-Package		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/22/2020	

Part 2 of 3

FLOURIDE SOFT MINT

sodium monofluorophosphate paste, dentifrice

Product Information

Item Code (Source)	NDC:79763-006
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU4080)	FLUORIDE ION	0.88 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
XYLITOL (UNII: VCQ006KQ1E)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
XANTHAN GUM (UNII: TTV12P4NEE)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
LEONTOPODIUM ALPINUM FLOWERING TOP (UNII: QQC1AK06RK)	
RHODODENDRON FERRUGINEUM WHOLE (UNII: FO6B1S7BZU)	
LACTIC ACID (UNII: 33X04XA5AT)	
WATER (UNII: 059QF0KO0R)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79763-006-01	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	07/22/2020	

Part 3 of 3

INSTANT BRIGHT AND WHITE CONCENTRATE

other oral hygiene products gel

Product Information

Route of Administration ORAL

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	CALCIUM CARBONATE (UNII: H0G9379FGK)	
INGR	CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
INGR	SODIUM HYDROXIDE (UNII: 55X04QC32I)	
INGR	CALCIUM GLYCEROPHOSPHATE (UNII: XW9Z12C1C)	
INGR	WATER (UNII: 059QF0K00R)	
INGR	HYDRATED SILICA (UNII: Y6O7T4G8P9)	
INGR	CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)	
INGR	FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
INGR	TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
INGR	POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
INGR	CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
INGR	SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
INGR	SORBITOL (UNII: 506T60A25R)	
INGR	PENTYLENE GLYCOL (UNII: 50C1307PZG)	
INGR	MANNITOL (UNII: 3OVL53L36A)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2.6 g in 1 BOTTLE, WITH APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic		07/23/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	07/22/2020	

Labeler - Swiss Shine Beauty AG (480422958)

Establishment

Name	Address	ID/FEI	Business Operations
System Kosmetik Produktionsgesellschaft für kosmetische Erzeugnisse mbH		328825757	manufacture(79763-004)

Establishment

Name	Address	ID/FEI	Business Operations
Marvinpac SA		482060329	pack(79763-004)

Revised: 8/2021

Swiss Shine Beauty AG