

**DENTAL KIT STRONG MINT- sodium monofluorophosphate  
vVardis 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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**Dental Kit Strong Mint**

Active Ingredients Purpose

sodium monofluorophosphate 0.88%  
(0.115% W/W fluoride Ion) Anticavity

Use

Aids in the prevention of dental cavities

**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.

**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.

- Adults and children 2 years of age and older: Brush teeth thoroughly, preferable 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, 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

Switzerland


Dental Kit by VVARDIS

One Toothbrush



One Fluoride toothpaste

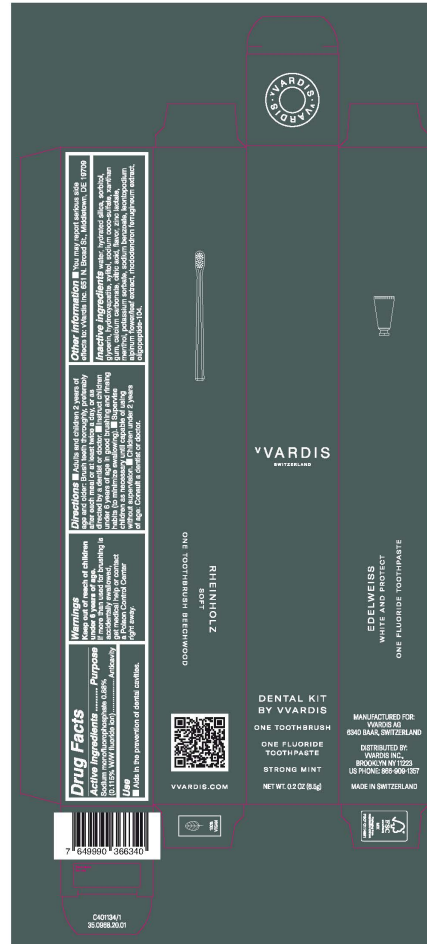
Strong Mint

NET. WT. 0.2 OZ (6.5g)

Product Dental Kit Strong	RELEASED
Packaging type SPM	Author / Date Philipp Gilgen / 02.11.2021
Internal reference / Version C4D1134/1	Reviewed by / Date Florent Deligny / 02.11.2021
Region <input type="checkbox"/> EU <input checked="" type="checkbox"/> US <input type="checkbox"/> others	
Supplier Etna	
Date 14.09.2021	

Paper:  
OLIN ROUGH EXTRA 300gsm

Pantone 560 U	
CMYK Black 100%	



## DENTAL KIT STRONG MINT

sodium monofluorophosphate kit

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:82615-003
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82615-	1 in 1 KIT; Type 9: Other Type of Part 3 Combination Product	02/01/2022	

**Quantity of Parts**

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	8.5 g
Part 2		1

**Part 1 of 2**

**SRONG MINT FLUORIDE**

sodium monofluorophosphate gel

**Product Information**

<b>Item Code (Source)</b>	NDC:82615-004
<b>Route of Administration</b>	DENTAL

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

**Packaging**

Item	Marketing	Marketing
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82615-004-01	6.5 g in 1 TUBE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/05/2022	

### Part 2 of 2

### TOOTHBRUSH

toothbrush, manual not applicable

### Product Information

Route of Administration	DENTAL
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### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Exempt device	EFW	03/05/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/04/2022	

**Labeler** - vWardis AG (480487038)

Revised: 3/2022

vWardis AG