

**DENTAL KIT SOFT 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.

Dental Kit Soft Mint

Active Ingredients Purpose

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

Use - Aids in the prevention of dental cavities.

Keep out of reach of children under 6 years age.

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.

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.

Other Information

You may report serious side effects to : vVardis, Inc.

651 N. Broad St., Middletown, DE 19709

Inactive Ingredients

water, hydrated silica, hydrogenated strach 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

vVARDIS

Switzerland

Dental Kit by VVARDIS

One Toothbrush

One Fluoride toothpaste

Soft Mint

NET. WT. 0.2 OZ (6.5g)

1	NDC:82615-001-01	1 in 1 KIT; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	03/07/2022
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Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 TUBE	6.5 g
Part 2		1

Part 1 of 2

SOFT MINT FLUORIDE

sodium monofluorophosphate gel

Product Information

Item Code (Source)	NDC:82615-002
Route of Administration	DENTAL

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
XANTHAN GUM (UNII: TTV12P4NEE)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
WATER (UNII: 059QF0KO0R)	
HYDRATED SILICA (UNII: Y607T4G8P9)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
TRIBASIC CALCIUM PHOSPHATE (UNII: 91D9GV0Z28)	
XYLITOL (UNII: VCQ006KQ1E)	
SODIUM COCO-SULFATE (UNII: 3599J29ANH)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
LEONTOPODIUM ALPINUM FLOWERING TOP (UNII: QQC1AK06RK)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
GLYCERIN (UNII: PDC6A3C0OX)	
RHODODENDRON FERRUGINEUM WHOLE (UNII: FO6B1S7BZU)	
LACTIC ACID (UNII: 33X04XA5AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82615-002-01	6.5 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/07/2022	

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	03/07/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	03/07/2022	

Labeler - WARDIS AG (480487038)