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 our 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

swallowing).

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

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, potasium 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)

Product
Dental Rit Soft

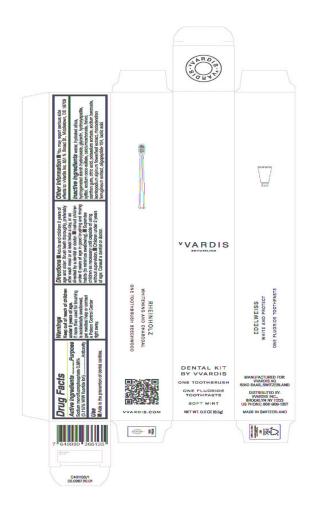
Packaging type
SPM
Author/Date
Philipp Gilgen / 02.11.2021

Internal reference / Version
C401133/1

Region
BUS Others
Supplies
Etna
Date
Date
SwitzerLAND
SwitzerLAND

Paper: OLIN ROUGH EXTRA 300gsm

смук Black 100%



Product Information Product Type HUMAN OTC DRUG Item Code (Source) Packaging # Item Code Package Description Package Description Marketing Start Date Marketing End Date

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

| 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 | | | |
|---------------------------------|---|----------------------|--------------------|
| I | Ingredient Name | Basis of Strength | Strength |
| l | SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O) | 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: Y6O7T4G8P9) | | | | |
| 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

| 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)

Revised: 3/2022 vVARDIS AG