

## **CURODONT PROTECT- stannous fluoride paste, dentifrice CREDENTIS 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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### **CREDENTIS (as PLD) - vVardis Professional - CURODONT PROTECT (72247-107)**

#### **ACTIVE INGREDIENTS**

STANNOUS FLUORIDE 0.454%  
(0.14% W/V FLUORIDE ION)

#### **PURPOSE**

ANTICAVITY AND ANTISENSITIVITY

#### **USE**

- AID IN THE PREVENTION OF DENTAL CAVITIES AND BUILDS INCREASING PROTECTION AGAINST PAINFUL SENSITIVITY OF THE TEETH.

#### **WARNINGS**

Stop use and ask a doctor if

- the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.
- pain/sensitivity still persists after 4 weeks of use.

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**

- 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.





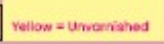
#### **OTHER INFORMATION**

This product may produce surface staining of the teeth. Adequate toothbrushing may

prevent these stains which are not harmful or permanent and may be removed by your dentist.

## INACTIVE INGREDIENTS

Sorbitol, Water, Hydrated Silica, Sodium Tripolyphosphate, Sodium Gluconate, Xylitol, Cellulose Gum, Oligopeptide-104, Sodium Hydroxide, Phosphoric Acid.

<p><b>V VARDIS</b> PROFESSIONAL SWITZERLAND</p> <p>Helps prevent dental cavities and builds increasing protection against painful sensitivity</p> <ul style="list-style-type: none"><li>• Aids in the prevention of dental cavities</li><li>• Remineralizes and strengthens enamel</li><li>• Ideal at home complement to Curodont™ Repair Fluoride Plus</li><li>• Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact</li></ul>	<p><b>CURODONT™ PROTECT</b> ANTICAVITY DENTIFRICE GEL FOR SENSITIVE TEETH</p> <p>Application</p> <ul style="list-style-type: none"><li>• Follow the directions in the Drug Facts box</li><li>• Scan the QR code on the side for more information</li></ul> 
<p>V VARDIS TECHNOLOGY</p>	<p><b>CURODONT™ PROTECT</b> Helps prevent dental cavities and builds increasing protection against painful sensitivity NET WT 0.13 OZ</p>
 <p>7 649990 366807</p>	<p>REF  </p> <p>LOT  Yellow = Unvarnished</p>

# Drug Facts

## Active ingredients

Stannous fluoride 0.454 %  
(0.14% w/v fluoride ion).....

## Purpose

Anticavity and Antisensitivity

**Use** ■ Aids in the prevention of dental cavities and builds increasing protection against painful sensitivity of the teeth.

## 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 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** Stop use and ask a doctor if ■ the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist. ■ pain/sensitivity still persists after 4 weeks of use. This product may produce surface staining of the teeth. Adequate toothbrushing may prevent these stains which are not harmful or permanent and may be removed by your dentist.

**Inactive ingredients** Sorbitol, Water, Hydrated Silica, Sodium Tripolyphosphate, Sodium Gluconate, Xylitol, Cellulose Gum, Oligopeptide-104, Sodium Hydroxide, Phosphoric Acid.

## CURODONT PROTECT

stannous fluoride paste, dentifrice

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72247-107
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Base of

Ingredient Name		Basis of Strength	Strength	
STANNOUS FLUORIDE (UNII: 3FTR44B32Q) (FLUORIDE ION - UNII:Q80VPU408O)		FLUORIDE ION	0.14 g in 100 g	
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
SORBITOL (UNII: 506T60A25R)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				
HYDRATED SILICA (UNII: Y6O7T4G8P9)				
SODIUM TRIPOLYPHOSPHATE (UNII: 5HK03SA80J)				
SODIUM GLUCONATE (UNII: R6Q3791S76)				
OLIGOPEPTIDE 104 (UNII: MUM5TLH7X6)				
XYLITOL (UNII: VCQ006KQ1E)				
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)				
PHOSPHORIC ACID (UNII: E4GA8884NN)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72247-107-13	1 in 1 BOX	08/27/2023	
1		0.13 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:72247-107-10	10 in 1 BOX	08/27/2023	
2		0.13 g in 1 TUBE; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part355	08/27/2023		

**Labeler** - CREDENTIS AG (485450345)

Revised: 8/2023

CREDENTIS AG