

DR. SHEFFIELD SENSITIVE CARE- sensitive tooth paste paste, dentifrice
Sheffield Pharmaceuticals LLC

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.

Drug Fact

Active Ingredient

Potassium Nitrate 5%

Purpose

Tooth desensitizer

Uses

Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets or contact.

Warnings

When using this product, if pain/sensitivity still persists after 4 weeks of use, please ask your dentist.

Stop Use and ask a Dentist, if the problem persists or worsens, Sensitive teeth may indicate a serious problem that may need prompt care of a dentist.

When using this product, if pain/sensitivity still persists after 4 weeks of use, stop use and contact your dentist.

Keep out of the reach of Children, If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years of age and older: Apply at least a 1 inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor.

Make sure to brush all sensitive areas of the teeth.

Children under 12 years of age: consult a dentist or doctor.

Inactive ingredients

Dicalcium Phosphate Dihydrate, Water (purified), Glycerin, Calcium Carbonate, Organic Cocos Nucifera (Coconut) oil, Quillaja Saponaria Wood Extract, Organic Aloe Barbadensis Leaf, Xylitol, Carrageenan, Xanthum Gum, Stevia Rebaudiana Leaf/Stem Extract, Yucca Schidigera Root extract, Quillaja Saponaria Bark Extract, Smilax Aristolochiaefolia Root extract, Dioscorea Villosa (Wild Yam) Root extract, Natural Peppermint flavor, Natural Menthol, Natural Spearmint Flavor, Natural Fennel Flavor, Iris Florentina (Orris) Root Powder, Propolis Extract, Organic Melaleuca Alternifolia(teatree) oil, Commiphora Myrrha (Myrrha) ResinExtract, Sodium Benzoate

Questions? Call 1-800-222-1087

Principal Primary Panel Tube 5.0 oz



The image shows the packaging for Dr. Sheffield's Premium Natural Toothpaste. The top left features the brand name 'Dr. Sheffield's' in a stylized font, with 'SINCE 1850' below it. A portrait of Dr. Washington Sheffield is enclosed in an ornate oval frame. Below the portrait, the text 'PREMIUM NATURAL TOOTHPASTE' is written in a decorative font. Further down, it says 'FLUORIDE-FREE' and 'RELIEVES SENSITIVE TEETH BY BUILDING PROTECTION AROUND THE NERVE'. A teal banner at the bottom left contains the words 'Sensitive Care' in a script font, with 'NATURAL MINT' underneath. At the very bottom, it states 'NET WT. 5 OZ (141 g)'. On the right side of the packaging, there is a detailed list of ingredients and instructions.

Active ingredient	Purpose
Potassium Iodate 5%	Tooth desensitizer

Uses

- Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact.

Warnings

- When using this product if pain/sensitivity still persists after 4 weeks of use, stop use and contact your dentist.
- Stop use and ask a dentist if the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.

Keep out of reach of children. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults and children 12 years of age and older: Apply at least a 1-inch strip of the product onto a soft-bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor. • Make sure to brush all sensitive areas of the teeth. • Children under 12 years of age: Consult a dentist or doctor.

Inactive ingredients

Dicalcium Phosphate Dihydrate, Water (purified), Vegetable Glycerin, Calcium Carbonate, Organic Cocon Nucifera (Coconut) Oil, Quilaja Saponaria Wood Extract, Organic Aloe Barbadosensis Leaf, Xylitol, Geraniol, Xanthan Gum, Stivola Rebaudiana Leaf/Stem Extract, Yucca Schottigera Root Extract, Quilaja Saponaria Bark Extract, Smilax Alabamica Root Extract, Dioscorea Villosa (Wild Yam) Root Extract, Natural Peppermint Flavor, Natural Menthol, Natural Spearmint Flavor, Natural Fennel Flavor, Iris Florentina (Oris) Root Powder, Propolis Extract, Organic Melaleuca Alternifolia (Tea Tree) Leaf Oil, Commiphora Myrrha (Myrrh) Resin Extract, Sodium Benzoate

Questions? Call 1-800-222-1087

Historically Natural

Dr. Sheffield would never have envisioned a future where toothpaste would be filled with synthetic substances.

Dr. Sheffield's Natural Toothpaste Contains:

- No Fluoride
- No Synthetic Detergents
- No Synthetic Foaming Agents
- No Artificial Preservatives
 - No Artificial Colors
 - No Artificial Flavors
- No Artificial Sweeteners
- No Genetically Modified Organisms
- No Animal By-Products or Testing.

Distributed by:
Sheffield Pharmaceuticals
170 Broad Street, New London, CT 06320
www.sheffieldpharma.com
1-800-222-1087
2501081

Dr. Sheffield Certified Natural Toothpaste

Sensitive Care Natural Mint

NET WT. 5 OZ (141g)

Dr. Sheffield's

SINCE
1850



FLUORIDE-FREE

RELIEVES SENSITIVE
TEETH BY BUILDING
PROTECTION AROUND
THE NERVE

*Sensitive
Care*

NATURAL MINT

NET WT. 5 OZ (141 g)

Active ingredient	Purpose
Fluorocin n trate 5%	Tooth desensitizer
Uses • Builds increasing protection against painful sensitivity of the teeth to cold, heat, acids, sweets, or contact.	
Warnings • When using this product if pain/sensitivity still persists after 4 weeks of use, stop use and contact your dentist. • Stop use and ask a dentist if the problem persists or worsens. Sensitive teeth may indicate a serious problem that may need prompt care by a dentist.	
Keep out of reach of children, if more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away.	
Directions • Adults and children 12 years of age and older: Apply at least a 1-inch strip of the product onto a soft bristle toothbrush. Brush teeth thoroughly for at least 1 minute twice a day (morning and evening) or as recommended by a dentist or doctor. • Water runs to brush all sensitive areas of the teeth. • Children under 12 years of age: Consult a dentist or doctor.	
Inactive ingredients: Dicalcium Phosphate Dihydrate, Water (purified), Vegetable Glycerin, Calcium Carbonate, Organic Cocos Nucifera (Coconut) Oil, Quillaja Saponaria Wood Extract, Organic Aloe Barbadensis Leaf, Xylitol, Carageenan, Xanthan Gum, Stevia Rebaudiana Leaf/Stem Extract, Yucca Schottigera Root Extract, Quillaja Saponaria Bark Extract, Smilax Aristolochifolia Root Extract, Dioscorea Villosa (Wild Yam) Root Extract, Natural Peppermint Flavor, Natural Menthol, Natural Spearmint Flavor, Natural Fennel Flavor, Iris Florentina (Orchid) Root Powder, Propolis Extract, Organic Melaleuca Alternifolia (Tea Tree) Leaf Oil, Compositans Myrtus (Myrtle) Resin Extract, Sodium Benzoate	
Questions? Call 1-800-222-1987	

Historically Natural

Dr. Sheffield would never have envisioned a future where toothpaste would be filled with synthetic substances.

Dr. Sheffield's Natural Toothpaste Contains:

- No Fluoride
- No Synthetic Detergents
- No Synthetic Foaming Agents
- No Artificial Preservatives
- No Artificial Colors
- No Artificial Flavors
- No Artificial Sweeteners
- No Genetically Modified Organisms
- No Animal By-Products or Testing.

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2501081

Principal Primary Panel Carton 5.0 oz



DR. SHEFFIELD SENSITIVE CARE

sensitive tooth paste paste, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11527-420
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
POTASSIUM NITRATE (UNII: RU45X2JN0Z) (NITRATE ION - UNII:T93E9Y2844)		POTASSIUM NITRATE	50 mg in 1 g

Inactive Ingredients			
Ingredient Name			Strength

CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)
WATER (UNII: 059QF0K00R)
GLYCERIN (UNII: PDC6A3C0OX)
CALCIUM CARBONATE (UNII: H0G9379FGK)
COCONUT OIL (UNII: Q9L0O73W7L)
QUILLAJA SAPONARIA WOOD (UNII: 1L8K0593B6)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
XYLITOL (UNII: VCQ006KQ1E)
CARRAGEENAN (UNII: 5C69YCD2YJ)
XANTHAN GUM (UNII: TTV12P4NEE)
STEVIA REBAUDIUNA LEAF (UNII: 6TC6NN0876)
YUCCA SCHIDIGERA ROOT (UNII: E2H9ET15AT)
SMILAX ARISTOLOCHIIFOLIA ROOT (UNII: NR100Y25G0)
DIOSCOREA VILLOSA ROOT (UNII: IWY3IWX2G8)
IRIS GERMANICA VAR. FLORENTINA ROOT (UNII: M30XO5X4XD)
PROPOLIS WAX (UNII: 6Y8XYV2NOF)
MELALEUCA ALTERNIFOLIA LEAF (UNII: G43C57162K)
COMMIPHORA MYRRHA TOP (UNII: N534J96ODY)

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11527-420-45	1 in 1 CARTON	05/15/2017	
1		141 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 not final	part356	05/15/2017	

Labeler - Sheffield Pharmaceuticals LLC (151177797)

Registrant - Sheffield Pharmaceuticals LLC (151177797)

Establishment

Name	Address	ID/FEI	Business Operations
Sheffield Pharmaceuticals LLC		151177797	manufacture(11527-420)