DENTAKOTES- dentakotes gel Rapha Pharmaceuticals, Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

ACTIVE INGREDIENTS

Methyl Salicylate 6x, Ferrum Phosphoricum 6x, Bellis Perennis 6x, Aconitum Napellus 6x

PURPOSE

Anti-Plaque, Anti-Gingivitis

USE

Helps to decrease the adhesion of bacterial deposits, bio-toxins, and the consequences of gingivitis.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children.

DIRECTIONS

Apply to natural teeth and dental prosthetics, bonds immediately.

WARNINGS

In case of overdose, seek medical attention or contact a Poison Control Center (1-800-222-1222) right away.

INACTIVE INGREDIENTS

Silicone Oil

OTHER INFORMATION

DentaKoteS™

DentaKote-S™ is a super hydrophobic prophylactic proprietary gel coating formulation. Used to help eliminate root sensitivity on natural teeth. It is a safe and effective homeopathic treatment. It provides immediate relief of cold-related sensitivity to the root surfaces in vital, non-diseased teeth (no underlying pathology). Supplied in a single disposable patient applicator for use on the exposed root surfaces of natural teeth due

to gum recession.

DentaKote- S^{TM} is a self-bonding silicone formulation developed by a dentist to be biocompatible, safe, and pH stable. It is proven effective with proper use, and the clinical guidelines are followed.

Benefits of DentaKoteS™

- Odorless & tasteless
- Improve & simplify oral hygiene habits
- Simple to apply by staff
- Eliminate root sensitivity instantly
- Some insurance coverage under "desensitizing agents"
- Passive revenue generator for the practice

PRINCIPAL DISPLAY PANEL



DENTAKOTES

dentakotes gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69953-553	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII: O414PZ4LPZ)	METHYL SALICYLATE	6 [hp_X] in 6 [hp_X]	
ACONITUM NAPELLUS (UNII: U0NQ8555JD) (ACONITUM NAPELLUS - UNII:U0NQ8555JD)	ACONITUM NAPELLUS	6 [hp_X] in 6 [hp_X]	
FERROSOFERRIC PHOSPHATE (UNII: 91GQH8I5F7) (FERROSOFERRIC PHOSPHATE - UNII:91GQH8I5F7)	FERROS OFERRIC PHOS PHATE	6 [hp_X] in 6 [hp_X]	
BELLIS PERENNIS (UNII: 2HU33I03UY) (BELLIS PERENNIS - UNII:2HU33I03UY)	BELLIS PERENNIS	6 [hp_X] in 6 [hp_X]	

Inactive Ingredients		
Ingredient Name	Strength	
DIMETHICONE (UNII: 92RU3N3Y1O)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
NDC:69953-553- 01	6 [hp_X] in 1 VIAL; Type 0: Not a Combination Product	01/18/2023		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved homeopathic		01/18/2023		

Labeler - Rapha Pharmaceuticals, Inc. (079804155)

Revised: 1/2023 Rapha Pharmaceuticals, Inc.