100 TOOTHPAST E NIGHT- sodium monofluorophosphate gel, dentifrice
MGRU

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.

ACTIVE INGREDIENT

Sodium Monofluorophosphate 0.75%

INACTIVE INGREDIENTS

D-Sorbitol Solution, Aqua, Silicon Dioxide, Chamomile Extract, Rhatany Essence, Sodium Cocoyl Glutamate, Carboxymethylcellulose Sodium, Peppermint Oil, Aqua Mint Flavor, Grapefruit Seed Extract, L-Menthol, Aluminium Chlorohydroxy Allantoinate, Xylitol, Enzymatically Modified Stevia, Green Tea Extract, Aloe Extract, Eucalyptus Extract, Sage Extract

PURPOSE

Nourishing, Soothing

WARNINGS

Adults and children 2 years of age and older: apply a 1-inch strip of product onto a toothbrush. Brush teeth thoroughly for 3 minutes three times a day (morning, afternoon, evening) or as recommended by a dentist. Do not swallow.

KEEP OUT OF REACH OF CHILDREN

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Uses

■ Provides a protection and relief action for healthier teeth and gum.
■ Helps fight and protect against cavities for healthier teeth.

Directions

■ Adults and children 2 years of age and older: Brush teeth thoroughly, preferably after each meal or three times a day, or as directed by a dentist or physician

■ Children 2 to 6 years: Use only a pea sized amount and supervise child's brushing and rinsing (to minimize swallowing)
■ Children under 2 years: Consult a dentist

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

100 TOOTHPAST E NIGHT

sodium monofluorophosphate gel, dentifrice

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81307-030
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Sodium Monofluorophosphate (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	0.75 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
Sorbitol (UNII: 506T60A25R)	
Water (UNII: 059QF0KO0R)	
Silicon Dioxide (UNII: ETJ7Z6XBU4)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81307-030-02	1 in 1 CARTON	12/01/2020	
1	NDC:81307-030-01	100 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	12/01/2020	

Labeler - MGRU (695672240)

Registrant - MGRU (695672240)

Establishment

Name	Address	ID/FEI	Business Operations
DONG IL PHARMS CO., LTD.		557810721	manufacture(81307-030)

Revised: 12/2020 MGRU