# 100 TOOTHPAST E MORNING- 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.

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#### ACTIVE INGREDIENT

Sodium Monofluorophosphate 0.75%

#### INACTIVE INGREDIENTS

D-Sorbitol Solution, Aqua, Silicon Dioxide, Sodium Cocoyl Glutamate, Carboxymethylcellulose Sodium, L-Menthol, Peppermint Oil, Aloe Extract, Spearmint Oil, Titanium Oxide, Soda Flavor, Xylitol, Enzymatically Modified Stevia, Grapefruit Seed Extract, Hydroxyapatite, Sage Extract, Chamomile Extract

### **PURPOSE**

Anti cavity

### **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

- Helps fight and protect against cavities for healthier teeth.
- Refreshes your day with a strong mint flavor, which leaves your mouth feeling fresh and clean.

## **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

# MGRU 100 TOOTHPASTE

## Mint Flavor Toothpaste

### **Drug Facts**

#### Active ingredients

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#### **Inactive ingredients**

D-Sorbitol Solution, Aqua, Silicon Dioxi de, Sodium Cocoyl Glutamate, Carboxy methylcellulose Sodium, L-Menthol, Pep permint Oil, Aloe Extract, Spearmint Oil, Titanium Oxide, Soda Flavor, Xylitol, Enzy matically Modified Stevia, Grapefruit Se ed Extract, Hydroxyapatite, Sage Extract, Chamomile Extract

[Distributor] MGRU CARE 1f 215-30 40th Ave bayside ny 11361, USA [Manufacturer] DONG IL PHARMS CO.,LTD. 26 Rinosandan-gil, Maengdong-myeon, Eumseong, S. Korea

3.53 fl. oz. (100 g)





Eco friendly



Ingredients



Non GMO



# 100 TOOTHPAST E MORNING

sodium monofluorophosphate gel, dentifrice

## **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:81307-010

Route of Administration ORAL

## **Active Ingredient/Active Moiety**

| Ingredient Name  | <b>Basis of Strength</b> | 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 DIO XIDE (UNII: ETJ7Z6 XBU4) |          |  |  |

|   | Packaging          |  |                             |                           |  |  |
|---|--------------------|--|-----------------------------|---------------------------|--|--|
| ı | # Item Code        | Package Description                                | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |  |  |
| ı | 1 NDC:81307-010-02 | 1 in 1 CARTON                                      | 12/01/2020                  |                           |  |  |
| ı | 1 NDC:81307-010-01 | 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                                  | 12/0 1/20 20         |                    |  |
|                       |  |                      |                    |  |

# **Labeler** - MGRU (695672240)

# Registrant - MGRU (695672240)

| Establishment            |         |           |                        |  |
|--------------------------|---------|-----------|------------------------|--|
| Name                     | Address | ID/FEI    | Business Operations    |  |
| DONG IL PHARMS CO., LTD. |         | 557810721 | manufacture(81307-010) |  |

Revised: 12/2020 MGRU