

## **DINOSAUR- sodium fluoride paste**

**LMZ**

**Reference Label Set Id: b196665d-b579-d0bc-e053-2a95a90a78e1**

*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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### **Plak Smacker**

#### **Active Ingredients**

Sodium Fluoride 0.24% Anti-Cavity  
(0.10% w/w fluoride ion) Toothpaste

#### **Purpose**

Anti-Cavity  
Toothpaste

#### **Use**

Aids in the prevention of cavities.

#### **Warnings**

If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

Keep out of reach of children under 6 years of age.

#### **Do Not Use**

Do not use if inner foil is torn, cut or missing.

#### **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 physician.

- Do not swallow.
- To minimize swallowing use a pea sized amount in children under 6 years.
- Supervise children's brushing until good habits are established.
- Children under 2 years of age, consult a dentist or physician.

## Inactive Ingredients

Sorbitol, Water, Hydrated Silica, PEG-8, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Sodium Saccharin, Sodium Benzoate, Xylitol, Trisodium Phosphate, Xanthan Gum, Acid Blue 9, Allura Red AC

## Questions or comments?

1-800-558-6684

24g NDC: 71775-070-54



## Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.24% .....	Anti-Cavity
(0.10% w/w fluoride ion).....	Toothpaste

**Use** Aids in the prevention of cavities.

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1-800-558-6684

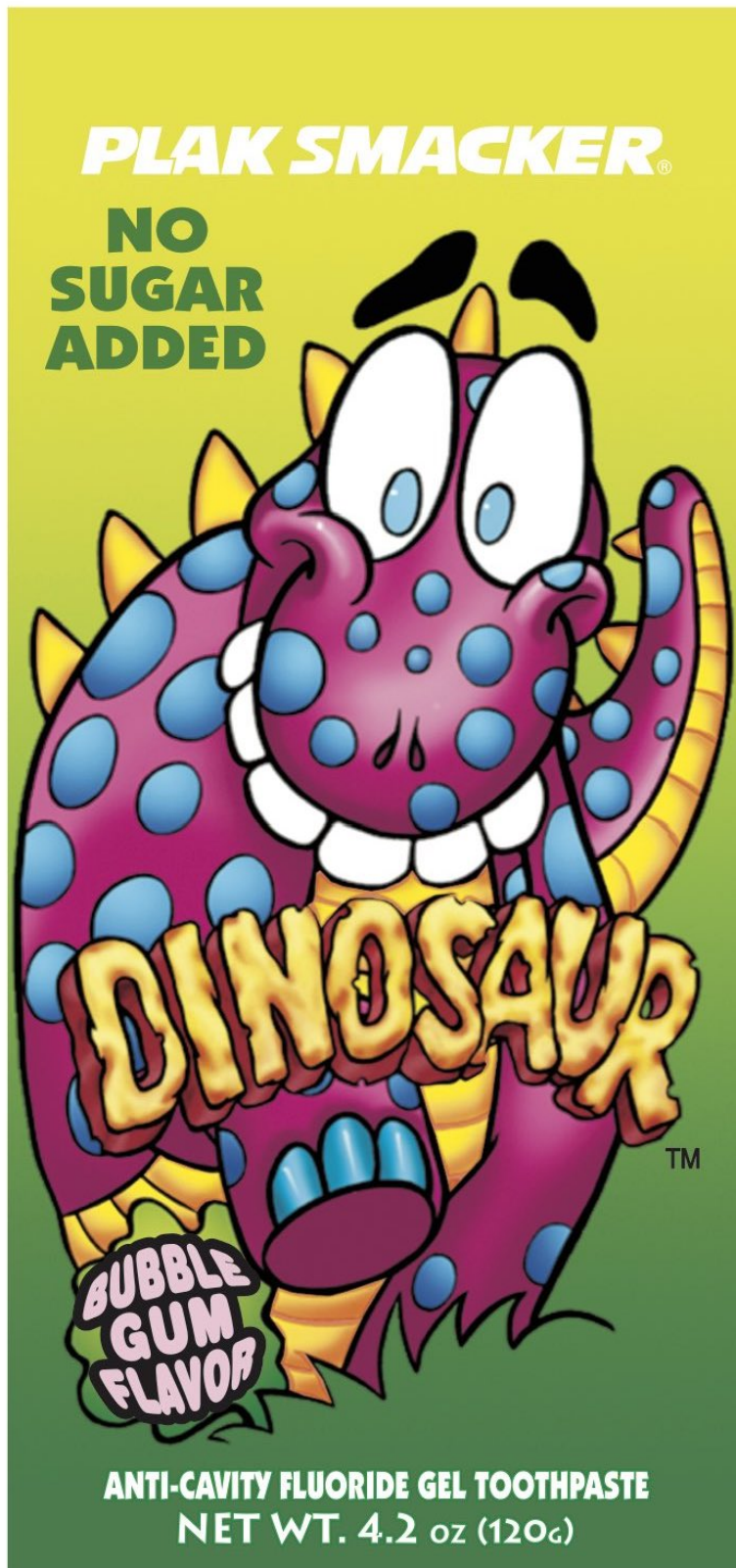
### Distributed by:

Young Innovations, Inc.  
2260 Wendt Street  
Algonquin, IL 60102 USA  
www.plaksmacker.com

REF 100049

Made in China  
DINO24G Rev.A

120g NDC: 71775-070-52



24g NDC: 71775-070-55

## Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.24% .....	Anti-Cavity
(0.10% w/w fluoride ion) .....	Toothpaste

### Use

Aids in the prevention of cavities.

### Warnings

**Keep out of reach of children under 6 years of age.** If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

**Do not use if inner foil is torn, cut or missing.**

### 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 physician.
- Do not swallow.
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### Inactive Ingredients

Sorbitol, Water, Hydrated Silica, PEG-8, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Sodium Saccharin, Sodium Benzoate, Xylitol, Trisodium Phosphate, Xanthan Gum, Acid Blue 9, Allura Red AC

### Questions or comments?

1-800-558-6684

Distributed by:  
Young Innovations, Inc.  
2260 Wendt Street  
Algonquin, IL 60102 USA  
www.plaksmacker.com

REF 00158

Made in China  
DINO120G Rev.A



## Drug Facts

Active Ingredient	Purpose
Sodium Fluoride 0.24% .....	Anti-Cavity
(0.10% w/w fluoride ion).....	Toothpaste

**Use** Aids in the prevention of cavities.

**Warnings** Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.

**Do not use if inner foil is torn, cut or missing.**

### 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 physician.
- Do not swallow. ■ To minimize swallowing use a pea sized amount in children under 6 years. ■ Supervise children's brushing until good habits are established. ■ Children under 2 years of age, consult a dentist or physician.

### Inactive Ingredients

Sorbitol, Water, Hydrated Silica, PEG-8, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Xanthan Gum, Xylitol, Sodium Saccharin, Sodium Benzoate, Trisodium Phosphate, Mica, Acid Blue 9

**Questions or comments?**  
1-800-558-6684

Distributed by:  
Young Innovations, Inc.  
2260 Wendt Street  
Algonquin, IL 60102 USA  
www.plaksmacker.com

REF 100050

Made in China

SHARK24G Rev.A

120g NDC: 71775-070-53



<b>Drug Facts</b>	
<b>Active Ingredient</b>	<b>Purpose</b>
Sodium Fluoride 0.24% (0.10% w/w fluoride ion)	..... Anti-Cavity ..... Toothpaste
<b>Use</b>	
Aids in the prevention of cavities.	
<b>Warnings</b>	
Keep out of reach of children under 6 years of age. If you accidentally swallow more than used for brushing, get medical help or contact a Poison Control Center immediately.	
Do not use if inner foil is torn, cut or missing.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ 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 physician.</li> <li>■ Do not swallow.</li> <li>■ To minimize swallowing use a pea sized amount in children under 6 years.</li> <li>■ Supervise children's brushing until good habits are established.</li> <li>■ Children under 2 years of age, consult a dentist or physician.</li> </ul>	
<b>Inactive Ingredients</b>	
Sorbitol, Water, Hydrated Silica, PEG-8, Sodium Lauryl Sulfate, Flavor, Cellulose Gum, Xanthan Gum, Xylitol, Sodium Saccharin, Sodium Benzoate, Trisodium Phosphate, Mica, Acid Blue 9	
<b>Questions or comments?</b>	
1-800-558-6684	

Distributed by:  
 Young Innovations, Inc.  
 2260 Wendt Street  
 Algonquin, IL 60102 USA  
 www.plaksmacker.com

**REF 00157**  
 Made in China  
 SHARK120G Rev.A

<b>DINOSAUR</b>			
sodium fluoride paste			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71775-070

**Route of Administration** DENTAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>SODIUM FLUORIDE</b> (UNII: 8ZYQ1474W7) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	100 mg in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>HYDRATED SILICA</b> (UNII: Y607T4G8P9)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>CARBOXYMETHYLCELLULOSE</b> (UNII: 05JZI7B19X)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>SACCHARIN SODIUM</b> (UNII: SB8ZUX40TY)	
<b>SODIUM PHOSPHATE, TRIBASIC, ANHYDROUS</b> (UNII: SX01TZO3QZ)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>ZANTHOXYLUM NITIDUM ROOT</b> (UNII: L2CQZ81759)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM LAUROYL SARCOSINATE</b> (UNII: 632GS99618)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>SODIUM COPPER CHLOROPHYLLIN</b> (UNII: 1D276TYV9O)	
<b>ETHYL MENTHANE CARBOXAMIDE</b> (UNII: 6S7S02945H)	
<b>CLINOPODIUM CHINENSE WHOLE</b> (UNII: 29350ODC51)	
<b>CHONDRUS CRISPUS</b> (UNII: OQS23HUA1X)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71775-070-54	24 g in 1 TUBE; Type 0: Not a Combination Product	01/22/2021	
2	NDC:71775-070-52	120 g in 1 TUBE; Type 0: Not a Combination Product	01/22/2021	
3	NDC:71775-070-55	24 g in 1 TUBE; Type 0: Not a Combination Product	04/30/2021	
4	NDC:71775-070-53	120 g in 1 TUBE; Type 0: Not a Combination Product	04/30/2021	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/22/2021	

**Labeler -** LMZ (654623156)

## **Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LMZ		654623156	manufacture(71775-070)

Revised: 5/2021

LMZ