

ORAL7 DRY MOUTH MOISTURIZING- sodium monofluorophosphate paste, dentifrice

Oral7 USA Operations Inc

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.

Oral7 Dry Mouth Moisturizing Toothpaste

Drug Facts

Active Ingredient

Sodium Monofluorophosphate 0.76% w/w (1000ppmF)

Purpose

Anti-cavity

Use

Aids in the prevention of dental cavities.

Warnings

Keep out of reach of children

under 6 years of age. If more than used for brushing is accidentally swallowed, get medical help or contact a Poison Control Center right away. If symptoms of dry mouth persist, consult a health care professional.

DO NOT use

if you are allergic to any of the ingredients.

Directions

Adults and Children 2 years of age and older

- Use 2-3 times a day, 7 days a week.
- Brush teeth thoroughly, preferably after each meal or at least twice a day, or as directed by a doctor or dentist.
- Instruct children under 6 years of age in good brushing and rinsing habits (to minimize swallowing). Supervise children as necessary until capable of using without supervision.

Children under 2 years of age: Consult a dentist or doctor.

Other Information

Store below 77° F (25° C).

Inactive ingredients

DICALCIUM PHOSPHATE, HYDROGENATED STARCH HYDROLYSATE, GLYCERIN, AQUA, SILICA, DEXTROSE MONOHYDRATE, HYDRATED SILICA, ISOCETETH-20, XYLITOL, SODIUM MONOFLUOROPHOSPHATE, XANTHAN GUM, MENTHA PIPERITA (PEPPERMINT OIL), SODIUM BENZOATE, LACTOPEROXIDASE, POTASSIUM THIOCYANATE, LACTOFERRIN, LYSOZYME, GLUCOSE OXIDASE, LIMONENE, CALCIUM LACTATE

Questions

or Comments? Tel.: +1 833-672-5787 weekdays or Email : info@oral7us.com / oral7us.com

Always follow the label

ORAL7

REAL DRY MOUTH RELIEF

TOOTHPASTE

Fluoride & Calcium

2.5 fl oz 75 ml (105g)

SUGAR FREE

Naturally Sweetened with Xylitol

Made in the EU

Oral7 International Pty. Ltd.

Suite 2, 15 Delawney Street

Balcatta, WA 6021 AUSTRALIA

USA & Canada

Oral7 U.S. (Op) Inc.info@oral7us.com

www.oral7us.com

ORAL7
boost the benefits of your saliva

TOOTHPASTE

Enjoy a
Healthy
Smile 😊

Love our
Toothpaste?
Get even better
results by adding
our Mouthwash,
Mouth Gel or
Mouth Spray to
your daily
routine :D

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Email: info@oral7us.com/oral7us.com

Always follow the label

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Oral7 International Pty. Ltd.
Suite 2, 15 Delawney Street
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oral7.com | info@oral7.com

USA & Canada
Oral7 U.S. (Op) Inc.
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ORAL7
boost the benefits of your saliva



**REAL
DRY MOUTH
RELIEF** ✓

TOOTHPASTE

**WITH
Active ENZYMES**

Fluoride & Calcium • NO SLS

2.5fl.oz. 75mL (105g) e

Seven
reasons to
love
ORAL7

- ✓ Extra beneficial for Dry Mouth sufferers
- ✓ With active enzymes to boost the benefits of healthy saliva
- ✓ Sugar & Saccharin Free
- ✓ Helps freshen breath
- ✓ Helps promote healthy gums
- ✓ Aids cleaning away the bacteria associated with bad breath, sore gums, cavities & plaque
- ✓ Calcium & Fluoride

Xylitol
SUGAR FREE
Naturally Sweetened with Xylitol

www.oral7.com

DRY MOUTH RELIEF.

Helps soothe & protect dry mouth tissue against minor irritations. Enzymes help inhibit odour causing bacteria and enhance gum health.

TOOTHPASTE
With Fluoride & Calcium • NO SLS

ORAL7
boost the benefits of your saliva



**Active WITH
ENZYMES**

- ✓ No SLS (Detergent)
 - ✓ Helps Freshen Breath
 - ✓ Sugar & Saccharin FREE
- 2.5fl.oz.
75mL (105g) e

C07P752019CTNLE1

ORAL7
boost the benefits of your saliva
Xylitol

REAL DRY MOUTH RELIEF



Active WITH ENZYMES

- ✓ Lasting Dry Mouth Relief
- ✓ Helps Freshen Breath
- ✓ Sugar & Saccharin FREE

2.5fl.oz.
75mL (105g) e

TOOTHPASTE

With Fluoride & Calcium • NO SLS

LONG-LASTING DRY MOUTH RELIEF.

Helps soothe & protect dry mouth tissue against minor irritations. Enzymes help inhibit odour causing bacteria and enhance gum health.

DIRECTIONS: Adults & children 6+ yrs: Brush thoroughly after each meal. For optimum results, rinse with Oral7[®] Mouthwash.

Children 2-6 yrs: Use a pea sized amount for supervised brushing to minimize swallowing. In case of intake of fluoride from other sources consult a dentist/doctor.

Keep out of reach of children. Do not use if seal is broken.
For children 12 years and under, use on the advice of a healthcare professional.
If symptoms of dry mouth persist, consult a healthcare professional.

CONTAINS NO SACCHARIN. - Store at room temperature.

INGREDIENTS: Dicalcium Phosphate, Hydrogenated Starch Hydrolysate, Glycerin, Aqua, Silica, Dextrose Monohydrate, Hydrated Silica, Isoceteth-20, Xylitol, Sodium Monofluorophosphate, Xanthan Gum, Mentha Piperita (Peppermint Oil), Sodium Benzoate, Lactoperoxidase, Potassium Thiocyanate, Lactoferrin, Lysozyme, Glucose Oxidase, Limonene, Calcium Lactate.
Contains: Sodium Monofluorophosphate 0.76% w/w (1000ppm F)

www.oral7.com

Made in the UK

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Balcatta WA 6021, Australia

C07T752019UTB1

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ORAL7 DRY MOUTH MOISTURIZING

sodium monofluorophosphate paste, dentifrice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81175-000
Route of Administration	DENTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM MONOFLUOROPHOSPHATE (UNII: C810JCZ56Q) (FLUORIDE ION - UNII:Q80VPU408O)	FLUORIDE ION	7.6 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
LACTOFERRIN, BOVINE (UNII: KG21X1090A)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
GLYCERIN (UNII: PDC6A3C0OX)	
HYDRATED SILICA (UNII: Y6O7T4G8P9)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISOCETETH-20 (UNII: O020065R7Z)	
XYLITOL (UNII: VCQ006KQ1E)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
MYELOPEROXIDASE (UNII: JQZ6YM58U5)	
MENTHA PIPERITA (UNII: 79M2M2UDA9)	
POTASSIUM THIOCYANATE (UNII: TM7213864A)	
LYSOZYME (UNII: 968JKA7T33)	
GLUCOSE OXIDASE (UNII: OT8392U5N1)	
CALCIUM LACTATE (UNII: 2URQ2N32W3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81175-000-02	75 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part355	06/01/2019	

Labeler - Ora7 USA Operations Inc (117789267)

Revised: 6/2021

Ora7 USA Operations Inc