POVI-ONE- povidone-iodine 10% topical liquid
Elevate Oral Care

Drug Facts
Active Ingredients

Drug Facts

Active ingredient (in each ampule) ***Purpose***

Povidone-iodine USP, 10% w/v.....Antiseptic

Uses
Purpose

Uses health-care antiseptic for preparation of the skin and oral tissues, first aid antiseptic to help prevent the risk of infection, clears bacteria that can cause infection ■ cuts ■ scrapes ■ burns

Warnings For External Use
Do Not Use

Warnings **For external use only**

Do not use ■ in the eyes ■ over large areas of the body ■ if you are allergic to povidone-iodine or any other ingredients in this preparation ■ more than one application per patient per month unless directed otherwise by a doctor ■ in children under 12 years of age unless directed by a dentist or doctor ■ if you have thyroid conditions

Stop Use And Ask A Doctor

Stop use and ask a doctor If ■ irritation, swelling, rash or fever develops, or redness occurs

Keep out of Reach of Children

Keep out of reach of children. If pregnant or breast feeding ask a health care professional before use. Do not swallow, expectorate (spit) extra material out. If more than one dose is swallowed, seek medical advice or contact a Poison Control Center right away.

Directions

Drug Facts (continued)

Directions

- Unscrew the cap from the Povi•One bottle.
- Dispense one or more drops into well #1 of the dappen dish. 1 drop for site specific, 2 for pediatric dentitions or larger area applications, 3 for full mouth.
- Replace the cap in the Povi•One Bottle.
- Dry the patient's teeth with gauze or a tissue.
- Apply a light application of Povi•One to the teeth and gums surrounding the teeth with a brush applicator.
    - Do not over-apply.
- Do not re-use the brush and mixing well.

Other Information

Other information

- Store at room temperature, 23°C ± 2°C. - when mixed with patient saliva concentration is diluted to 0.5%

Inactive Ingredients

Inactive ingredients

Citric Acid, Disodium Phosphate, Glycerin, Purified Water, Sodium Citrate, Tween 80

Contents

Contents 1 - (8 mL) Bottle Povidone Iodine 10%

Questions?

Questions? 877-866-9113 (8:30 am - 5 pm, EST, Mon-Fri) or visit *www.elevateoralcare.com*.

Instructions for Use

Drug Facts (continued)

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Dosage and Administration

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Povi-One Solution
Outside Box label

NDC 57511-0611-2

elevate ORAL CARE®

Povi•One™

10% Povidone-Iodine

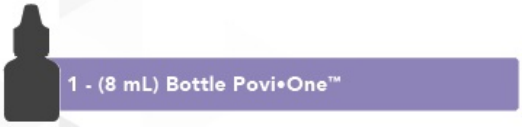
Oral Antiseptic

FluoriMax®

2.5% Sodium Fluoride Varnish

With Hydroxyapatite

CONVENIENCE KIT



1 - (8 mL) Bottle Povi•One™

1 - (8 mL) Bottle FluoriMax® Varnish

Rx Only

Contents:
1 - (8 mL) Bottle Povidone Iodine 10%
1 - (8 mL) Sodium Fluoride Varnish
150 - Applicator Brushes
150 - Mixing Wells
2 - Strap Caps

Povi•One™
10% Povidone-Iodine
Oral Antiseptic

IMPORTANT:
FluoriMax Varnish directions for use inside.

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Questions/Comments: 1-877-866-9113
Visit www.elevateoralcare.com

Packaged by and manufactured for
Elevate Oral Care, LLC.
346 Pike Road, Suite S
West Palm Beach, FL 33411, USA

ELEE70.092024

POVI-ONE

povidone-iodine 10% topical liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:57511-0611(NDC:68599-3500)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1 mg in 10 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics			
Color	brown (Liquid)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:57511-0611-2	8 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	12/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	12/13/2024	

Labeler - Elevate Oral Care (002863526)

Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	relabel(57511-0611) , repack(57511-0611)

Revised: 11/2024

Elevate Oral Care