

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

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**Povi-One**

**Drug Facts**  
**Active Ingredients**

***Drug Facts***

<b><i>Active ingredient (in each ampule)</i></b>	<b><i>Purpose</i></b>
Povidone-iodine USP, 10% w/v.....	Antiseptic

**Uses**  
**Purpose**

***Uses*** For preparation of the oral mucosa prior to injection, dental surgery, or tooth extraction ■ Reduces oral microorganisms prior to dental procedures ■ For professional dental infection control after proper dilution

**Warning For External Use**  
**Do Not Use**

***Warnings For external use only***

For professional dental use only, use only under the supervision of a dental professional ■ Not for prolonged or repeated use unless directed by a dentist or physician ■ Do not use in individuals with known iodine sensitivity ■ Avoid swallowing; if swallowed seek medical attention immediately ■ Do not use in children under 12 years of age unless directed by a dentist or doctor ■ Do not use 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

### ***Directions***

- Remove one ampule (caramel-colored container) and one brush (clear adapter) from the box.
- Screw the brush into the threaded end of the ampule until you hear a “pop” which opens the ampule.
- 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.
  - Do not over-apply. Often, wetting the bristles before applying to teeth is sufficient to deliver the product.
  - You will likely have extra material in the ampule when finished. There is no need to use the extra material.
- Discard the ampule. Do not re-use the product.
- Follow your dental or medical professional instructions for frequency of application. **Do not use more than one ampule each month unless instructed by a dental or medical professional.**

## Other Information

### ***Other information***

- Store at room temperature, 25°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** 6 unit-dose applicators, each containing 0.45 mL

## **Questions?**

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

## **Instructions for Use**

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**INSTRUCTIONS FOR USE:**



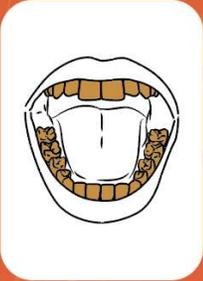
1. Remove one ampule (caramel-colored container) and one brush (clear adapter) from the box. Screw the brush into the threaded end of the ampule until you hear a "pop" which opens the ampule.



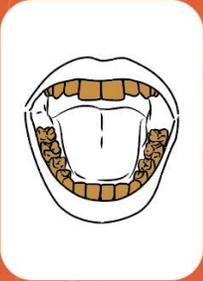
2a. Dry the patient's teeth with gauze or a tissue.



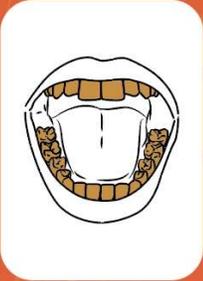
2b. Squeeze ampule over gauze or tissue to wet bristles prior to application.



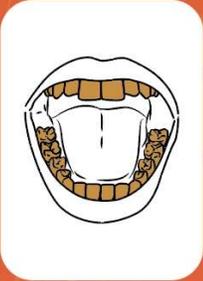
3a. Apply a light application of Povi-One™ to the teeth and gums.



3b. Do not over apply. With the bristles wet, there is no need to squeeze extra material out of the ampule during application.



4a. Continue to rewet bristles over gauze or tissue in between each section.



4b. Continue across all teeth. Keep mouth open for ten seconds after application is complete.

Follow your dental or medical professional instructions for frequency of application. Do not use more than one ampule each month unless instructed by a dental or medical professional.

## **Drug Facts Other Information**



## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:57511-0611(NDC:68599-3500)
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>POVIDONE-IODINE</b> (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1 mg in 10 mL

## Inactive Ingredients

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

## Product Characteristics

<b>Color</b>	brown (liquid)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:57511-0611-1	6 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	03/01/2023	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M022	03/01/2023	

**Labeler** - Elevate Oral Care (002863526)

## Establishment

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

