

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

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**Povi-One**

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

<b><i>Drug Facts</i></b>	
<b><i>Active ingredient (in each ampule)</i></b>	<b><i>Purpose</i></b>
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

**Warning 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 unit per patient per month unless directed otherwise by a doctor  
**Stop use and ask a doctor if** irritation or redness occurs.  
**Keep out of reach of children.** 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.

**Stop Use And Ask A Doctor**

**Stop use and ask a doctor if** irritation or redness occurs.

## Keep Out of Reach of Children

**Keep out of reach of children.** 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

### ***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 unit per patient per month unless directed otherwise by a doctor

## 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?**

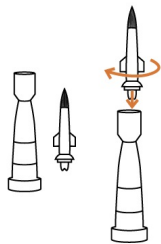
**Questions?** 877-866-9113 (8:30am-5pm, EST, Mon-Fri) or visit [www.elevateoralcare.com](http://www.elevateoralcare.com).

## **Instructions for Use**

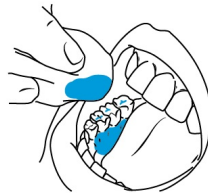
**Povi-One™**  
10% Povidone-iodine



### 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.



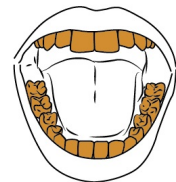
2a. Dry the patient's teeth with gauze or a tissue.

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



3. 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**

***Drug Facts*** (continued)

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***Other information***

- Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

**Povi-One Soution**  
**Outside box label**

**Povi-One**  
10% Povidone-iodine Antiseptic



- Oral Antimicrobial
- Oral Antiseptic
- Kills Germs
- Patient Friendly Flow-Thru™ Ampules

6  
Treatments

<b>Drug Facts</b>	
<b>Active ingredient (in each ampule)</b> Povidone-iodine USP, 10% w/v	<b>Purpose</b> Antiseptic
<b>Uses</b> 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	
<b>Warnings For external use only</b> <b>Do not use</b> ■ 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 unit per patient per month unless directed otherwise by a doctor. <b>Stop use and ask a doctor if irritation or redness occurs.</b> <b>Keep out of reach of children.</b> 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.	
<b>Directions</b> ■ 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. <b>Do not use more than one ampule each month unless instructed by a dental or medical professional.</b>	

<b>Drug Facts (continued)</b>
<b>Other information</b> ■ Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
<b>Inactive ingredients</b> Citric Acid, Disodium Phosphate, Glycerin, Purified Water, Sodium Citrate, Tween 80
<b>Contents</b> 6 unit-dose applicators, each containing 0.45 mL
<b>Questions?</b> 877-866-9113 (8:30am-5pm, EST, Mon-Fri) or visit <a href="http://www.elevateoralcare.com">www.elevateoralcare.com</a> .



elevate  
**Povi-One**  
10% Povidone-iodine  
6  
Treatments

elevate  
**Povi-One**  
10% Povidone-iodine



West Palm Beach, FL 33411  
Elevate Oral Care, LLC

Made in USA  
Povi-One is a trademark of  
Elevate Oral Care, LLC.

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ELEF78-10212021

Visit [www.elevateoralcare.com](http://www.elevateoralcare.com)  
1-877-866-9113  
Questions/Comments:



NDC 57511-0611-1

**Povi-One**  
10% Povidone-iodine

6  
Treatments

6 Ampules | NET Vol. 0.45 mL (per ampule)

**POVI-ONE**

povidone-iodine 10% topical liquid

**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**

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

**Inactive Ingredients**

Ingredient Name	Strength
<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**

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

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	505G(a)(3)	03/01/2023	

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

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