

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

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.

Pove-One

Drug Facts
Active Ingredient

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

Uses

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

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

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

Drug Facts (continued)

Other information

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

Inactive Ingredients

Inactive ingredients

Citric Acid, Disodium Phosphate, Glycerin, Nonoxynol-9, Sodium Hydroxide, Purified Water

Contents

Contents 6 unit-dose applicators, each containing 0.2 mL

Questions?

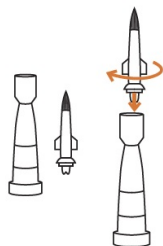
Questions? 877-866-9113 (8:30am-5pm, EST, Mon-Fri) or visit www.elevateoralcare.com.

Instructions For Use:

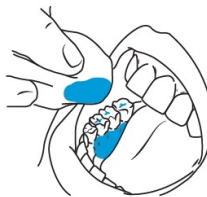
Povi•One™
10% Povidone-iodine



INSTRUCTIONS FOR USE:

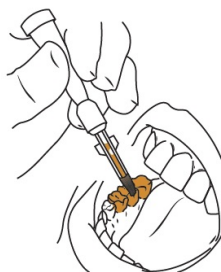


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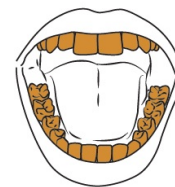
2a. Dry the patient's teeth with gauze or a tissue.

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 Panel

Drug Facts

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

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

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Drug Facts (continued)

Other information

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Inactive ingredients

Citric Acid, Disodium Phosphate, Glycerin, Nonoxynol-9, Sodium Hydroxide, Purified Water

Contents 6 unit-dose applicators, each containing 0.2 mL

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

Povi-One Solution 0.2ml X 6 Ampules
NDC: 57511-0610-1

Povi-One
10% Povidone-iodine Antiseptic

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

6
Treatments

<p>Drug Facts</p> <p>Active ingredient (in each ampule) Povidone-iodine USP, 10% w/v.....Purpose Antiseptic</p> <p>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</p> <p>Warnings For external use only</p> <p>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</p> <p>Stop use and ask a doctor if irritation or redness occurs.</p> <p>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.</p> <p>Directions</p> <ul style="list-style-type: none"> ■ 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. <ul style="list-style-type: none"> ■ 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. 	<p>Drug Facts (continued)</p> <p>Other information</p> <p>■ Store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)</p> <p>Inactive ingredients</p> <p>Citric Acid, Disodium Phosphate, Glycerin, Nonoxynol-9, Sodium Hydroxide, Purified Water</p> <p>Contents 6 unit-dose applicators, each containing 0.2 mL</p> <p>Questions? 877-866-9113 (8:30am-5pm, EST, Mon-Fri) or visit www.elevateoralcare.com.</p>
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6
Treatments

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Treatments

Povi-One
10% Povidone-iodine

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Treatments

Made in USA

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ELEVATE ORAL CARE, LLC

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www.elevateoralcare.com

Povi•One™

10% Povidone-iodine

6
Treatments

6 Ampules | NET Vol. 0.2 mL (per ampule)

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.

4a. Continue to wet brushes over gauze or tissue in between each section.

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



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

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

1. Remove one ampule (carmel-colored content) 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.

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

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

INSTRUCTIONS FOR USE:

POVI-ONE

povidone-iodine 10% topical liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57511-0610(NDC:0395-2325)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZ U99M) (IODINE - UNII:9679TC07X4)	IODINE	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
NONOXYNOL-2 (UNII: U4A966MO25)	
WATER (UNII: 059QF0KO0R)	

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:57511-0610-1	6 mL in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	05/02/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/02/2022	

Labeler - Elevate Oral Care (002863526)

Registrant - Elevate Oral Care (002863526)

Establishment

Name	Address	ID/FEI	Business Operations
Elevate Oral Care		002863526	relabel(57511-0610) , repack(57511-0610)

Revised: 3/2022

Elevate Oral Care