

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

Drug Facts
Active Ingredients

Drug Facts

Active ingredient

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

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

Drug Facts
Directions

Drug Facts (continued)

Directions

- Dispense 8 drops into a dappen dish
- Apply to treatment sites with a micro-brush or flock tip applicator for 30 seconds
- Expectorate excess material
- Do not rinse with water immediately after use unless advised
- This method dilutes when mixed with saliva to 0.05% iodine solutions

Directions: Dilution Instructions

- Dilute 1 part concentrate with 19 parts sterile or purified water to make a 0.5% povidone-iodine solution (0.05% available iodine)
 - Apply 10 to 20 milliliters of solution to the operative site
 - Instruct the patient to rinse for 30 seconds and then spit out
 - With a standard syringe and a blunt, angulated needle, irrigate the operative site and the surrounding gingival mucosa for 1 minute with 10 to 20 milliliters of the solution
 - Instruct the patient to spit out the solution after the irrigation procedure
 - Do not rinse with water immediately after use unless advised
-

Other Information

Other information

- Store at room temperature, 23°C ± 2°C

Inactive Ingredients

Drug Facts (continued)

Inactive ingredients

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

Contents

Contents 1 - (8 mL) Bottle of 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

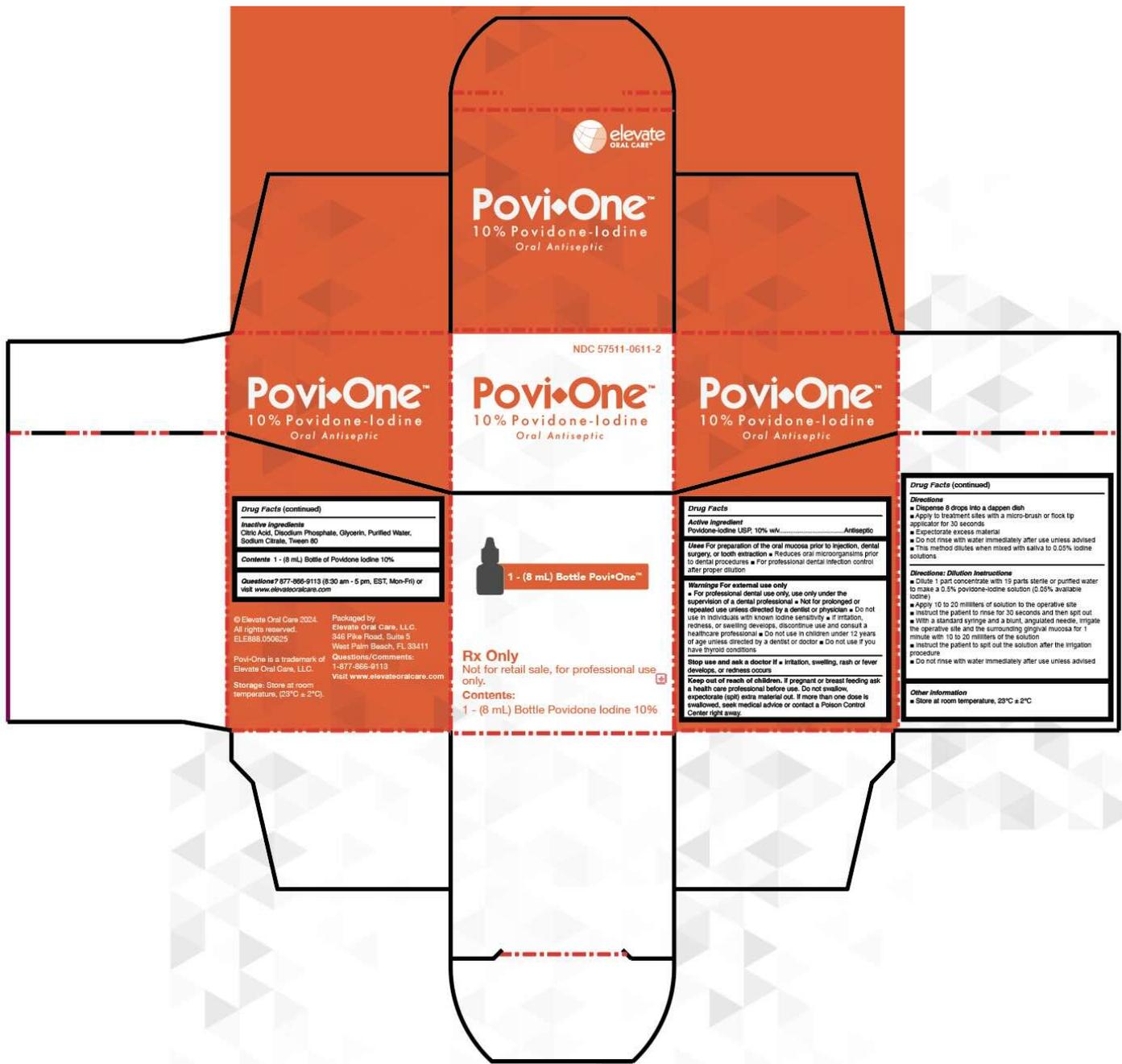
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Povi-One
Outside Box label



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	M022	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: 9/2025

Elevate Oral Care