

**ANTISEPTIC PATIENT PREOPERATIVE SKIN PREPARATION AND SURGICAL
HAND SCRUB- povidone-iodine solution
Degasa SA De CV**

**degasa Antiseptic Patient Preoperative Skin Preparation and Surgical Hand
Scrub Povidone Iodine 7.5%**

Active Ingredient

Povidone Iodine 7.5%

Purpose

Antiseptic

Uses

Patient preoperative skin preparation:

Surgical hand scrub:

- For preparation of the skin prior to surgery
- Helps reduce bacteria that potentially can cause skin infection
- Significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care

WARNINGS: For External Use Only

Do not use

Stop use and ask a doctor if

- In the eyes
- Heat prior to application
- On individuals who are allergic or sensitive to Iodine
- Irritation and redness develop
- If condition persists for more than 72 hours consult a doctor

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

Patient preoperative skin preparation:

Surgical hand scrub:

- Clean the area

- Apply product to the operative site prior to surgery
- Scrub thoroughly for 5 minutes
- Rinse off with a sterile gauze saturated with water
- Clean under nails with a nail pick. Nail should be maintained with a 1 millimeter free edge
- Wet hands and forearms
- Apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- Scub thoroughly for 5 minutes with a sterile brush
- Paying particular attention to the nails, cuticles, and interdigital spaces
- Rinse and repeat scrub

Other information

Store at room temperature 20-25°C (68-77°F)

Inactive Ingredients

Disodium Phosphate, Glycerin, Hidroxyethylcellulose, Monoethanolamine, Dionized Water

Package Labeling

| <p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Povidone- Iodine 7.5% (equivalent to 0.75% available Iodine)</td> <td>Antiseptic</td> </tr> </tbody> </table> <p>Inactive ingredients Disodium phosphate, Glycerin, Hydroxy Ethyl Cellulose, Monoethanolamine, Deionized Water.</p> <p>Uses Patient preoperative skin preparation: for preparation of the skin prior to surgery, helps reduce bacteria that potentially can cause skin infection. Surgical hand scrub: significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care.</p> <p>Warnings: For external use only</p> <p>Do not use: In the eyes, heat prior to application, on individuals who are allergic or sensitive to Iodine.</p> <p>Stop use and ask a doctor if Irritation and redness develop and if conditions persists for more than 72 hours consult a doctor.</p> <p>Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away</p> | Active ingredient | Purpose | Povidone- Iodine 7.5% (equivalent to 0.75% available Iodine) | Antiseptic | <p>NDC 67326-352-08</p>  <p>Antiseptic Patient Preoperative Skin Preparation and Surgical Hand Scrub</p> <p>7.5% POVIDONE IODINE</p> <p>NET CONTENTS 4 Fl. oz. (118 mL)</p> | <p>Directions</p> <p>For preparation of the skin prior to surgery</p> <p>Patient preoperative skin preparation : 1.Clean the area, 2. Apply product to the operative site prior to surgery, 3. Scrub thoroughly for 5 minutes, 4. Rinse off with a sterile gauze saturated with water.</p> <p>Surgical hand scrub: 1. Clean under nails with a nail pick, 2.Nail should be maintained with 1 millimeter free edge, 3.Wet hands and forearms, 4.Apply 5 milliliters (teaspoonful) or palmful to hands and forearms, 5.Scrub thoroughly for 5 minutes with a sterile brush, 6.Paying particular attention to the nails, cuticles, and interdigital spaces, 7.Rinse and repeat scrub</p> <p>Other information</p> <p>Store at room temperature 20-25° C (68-77°F)</p> <p>Questions ?</p> <p>956 728-8899</p> |
|--|-------------------|---------|---|------------|---|---|
| Active ingredient | Purpose | | | | | |
| Povidone- Iodine 7.5% (equivalent to 0.75% available Iodine) | Antiseptic | | | | | |



Made in Mexico
Manufactured by: Degasa, S. A. de C. V.
Calle 13 Este No. 580, Civac, Jiutepec, Morelos.
C.P. 62578. Mexico

ANTISEPTIC PATIENT PREOPERATIVE SKIN PREPARATION AND SURGICAL HAND SCRUB
povidone-iodine solution

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:67326-352 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4) | IODINE | 75 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| MONOETHANOLAMINE (UNII: 5KV86114PT) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:67326-352-07 | 48 in 1 CASE | 08/13/2015 | |
| 1 | | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:67326-352-08 | 48 in 1 CASE | 08/13/2015 | |
| 2 | | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 3 | NDC:67326-352-06 | 24 in 1 CASE | 08/13/2015 | |
| 3 | | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 4 | NDC:67326-352-03 | 24 in 1 CASE | 08/13/2015 | |
| 4 | | 474 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 5 | NDC:67326-352-05 | 12 in 1 CASE | 08/13/2015 | |
| 5 | | 948 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| OTC Monograph Drug | 505G(a)(3) | 08/13/2015 | |

Labeler - Degasa SA De CV (812771980)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|------------------------|
| Degasa, S.A. de C.V. | | 812771980 | manufacture(67326-352) |

Revised: 11/2023

Degasa SA De CV