

3M DURAPREP SURGICAL- iodine povacrylex and isopropyl alcohol solution

Solventum US OpCo LLC

Drug Facts

Active ingredients

Iodine povacrylex (0.7% available iodine)

Isopropyl alcohol, 74% w/w

Purpose

Antiseptic

Antiseptic

Uses

patient preoperative skin preparation:

- for preparation of the skin prior to surgery
- helps reduce bacteria that potentially can cause skin infection

Warnings

For external use only. Flammable, keep away from fire or flame.

To reduce the risk of fire, PREP CAREFULLY:

- do not use 26-mL applicator for head and neck surgery
- do not use on an area smaller than 8 in. x 10 in. Use a small applicator instead.
- solution contains alcohol and gives off flammable vapors
- do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- do not allow solution to pool
- remove solution-stained material from prep area

Do not use

- on patients with known allergies to iodine or any other ingredients in this product
- on open wounds, on mucous membranes, or as a general skin cleanser
- in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism

When using this product

- keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and

remain. If contact occurs, flush with cold water right away and contact a doctor.

- to avoid skin injury, care should be taken when removing drapes, tapes, etc...applied over film
- use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn

Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions (follow all directions for use)

- at the end of the prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available.

Getting Patient Ready for Solution:

- use in well-ventilated area
- do not microwave or heat the solution applicator
- apply to clean, completely dry, residue-free, intact skin
- when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues.

Activating the Applicator:

- with sponge face parallel to the floor, press the cap end of the applicator. Solution will begin to flow into the sponge.
- wait for fluid level to reach indicator line of applicator barrel

When Applying Solution:

- **DO NOT SCRUB.** Paint a single, uniform application and do not reprep area.
- **do not allow solution to pool.** Use sponge applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze.
- clean umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.)
- tuck prep towels as needed under both sides of the neck to absorb excess solution. Remove towels before draping.
- avoid getting solution into hairy areas. **Wet hair is flammable.** Hair may take up to 1 hour to dry.
- when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself.

After Applying Solution:

- to reduce the risk of fire, **wait until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair).** Solution will turn from a shiny to a dull appearance on skin alerting the user that the solution is completely dry and no longer flammable.

While Waiting for Solution to Completely Dry:

- do not drape or use ignition source (e.g., cautery, laser)
- check for pooled solution. Use sterile gauze to soak up pooled solution.
- Do not blot because it may remove solution from skin.
- remove solution-stained materials. Replace if necessary.

After Solution is Completely Dry:

- to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all solution-stained materials are removed
- if incise drapes are used, apply directly to dry prep. On completion of surgical procedure, removal of incise drape will remove film.
- apply dressing following standard practices

Other information

- store between 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- solution is not water soluble and may stain. Therefore, avoid contact with reusable items (basins, instruments).

Inactive ingredients

ethyl alcohol, water

Questions?

call 1-800-228-3957 (Monday to Friday 7AM – 6PM CST). www.3M.com.

Principle Display Panel - 26 mL Applicator Label

3M

STERILE EO

NDC 17518-011-08

Do Not Reuse

1. PRESS CAP

DOWN

2. PAINT, DO

NOT SCRUB

DuraPrep™

Surgical Solution

Iodine Povacrylex (0.7% Available Iodine) and **Isopropyl Alcohol** (74% w/w)

Patient Preoperative Skin Preparation **For large prep areas below the neck**

Non-Sterile Solution

Applicator is sterile if package is intact

REF 8630 0.9 fl oz • 26 mL

External Use Only

Professional Use Only

Read Drug Facts Information before use.

Made in U.S.A. by **3M Health Care**

2510 Conway Ave., St. Paul, MN 55144

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Principal Display Panel - 26 mL Insert Label

3M

STERILE EO

NDC 17518-011-08

MAL09032040XR

DuraPrep™

Surgical Solution

Iodine Povacrylex (0.7% Available Iodine)

and Isopropyl Alcohol (74% w/w)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

For large prep areas below the neck

Do Not Reuse

Latex-Free

Not Made With Natural Rubber Latex

Single Use

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.9 fl oz (26 mL) of solution which covers a 15 in x 30 in area (approximately from shoulder to groin in an average size adult).

For procedures requiring less coverage, a smaller applicator is available (8635). It contains 0.2 fl oz (6 mL) of solution which covers an approximate 8 in x 10 in area. Do not use more than required for the area.

3M recommends all users participate in product in-service training prior to use.

In-servicing is available on video, from your 3M sales representative, or at the 3M website (www.3M.com).

REF 8630 0.9 fl oz • 26 mL

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3M™ DuraPrep™ Surgical Solution 8630

Drug Facts	
Active ingredients Iodine Povacrylex (0.7% available iodine) Isopropyl alcohol, 74% w/w	Purpose Antiseptic Antiseptic
Uses patient preoperative skin preparation: • for preparation of the skin prior to surgery • helps reduce bacteria that potentially can cause skin infection	
Warnings For external use only. Flammable, keep away from fire or flame. To reduce the risk of fire, PREP CAREFULLY: <ul style="list-style-type: none"> do not use 26 mL applicator for head and neck surgery. do not use on an area smaller than 8 in x 10 in. Use a small applicator instead. solution contains alcohol and gives off flammable vapors. do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). avoid getting solution into hairy areas. Wet hair is flammable. Hair may take up to 1 hour to dry. do not allow solution to pool. remove solution-stained material from prep area. Do not use <ul style="list-style-type: none"> on patients with known allergies to iodine or any other ingredients in this product on open wounds, on mucous membranes, or as a general skin cleanser in infants less than 2 months old due to the risk of excessive skin irritation and transient hypothyroidism When using this product <ul style="list-style-type: none"> keep out of eyes, ears, and mouth. May cause serious injury if permitted to enter and remain. If contact occurs, flush with cold water right away and contact a doctor. to avoid skin injury, care should be taken when removing drapes, tapes, etc., applied over film use with caution in women who are breast-feeding due to the potential for transient hypothyroidism in the nursing newborn Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition. On rare occasions, use of this product has been associated with skin blistering. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions (follow all directions for use) <ul style="list-style-type: none"> at the end of the prep, discard any portion of the solution which is not required to cover the prep area. It is not necessary to use the entire amount available. Getting Patient Ready for Solution: <ul style="list-style-type: none"> use in well-ventilated area do not microwave or heat the solution applicator apply to clean, completely dry, residue-free, intact skin when hair removal is necessary, use a surgical clipper on the morning of the surgery. If a wet shave is used, thoroughly remove all soap residues. Activating the Applicator: <ul style="list-style-type: none"> with sponge face parallel to the floor, press the cap end of the applicator. Solution will begin to flow into the sponge. wait for fluid level to reach indicator line of applicator barrel When Applying Solution: <ul style="list-style-type: none"> DO NOT SCRUB. Paint a single, uniform application and do not prep area. do not allow solution to pool. Use sponge applicator to absorb excess solution and continue to apply a uniform coating. If solution accidentally gets outside of prep area, remove excess with gauze, clean umbilicus with enclosed swabs when applicable. (Moisten swabs by pressing against solution-soaked sponge applicator.) tuck prep towels as needed under both sides of the neck to absorb excess solution. Remove towels before draping. avoid getting solution into hairy areas. Wet hair is flammable. Hair may take up to 1 hour to dry. when prepping skin folds, toes, or fingers, use a sterile-gloved hand to hold skin apart until completely dry. Otherwise, skin may adhere to itself. to reduce the risk of fire, wait until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Solution will turn from a shiny to a dull appearance on skin alerting the user that the solution is completely dry and no longer flammable. While Waiting for Solution to Completely Dry: <ul style="list-style-type: none"> do not drape or use ignition source (e.g., cautery, laser) check for pooled solution. Use sterile gauze to soak up pooled solution. do not blot because it may remove solution from skin. remove solution-stained materials. Replace if necessary. After Solution Is Completely Dry: <ul style="list-style-type: none"> to reduce the risk of fire, begin draping and/or using cautery only after solution is completely dry and all solution-stained materials are removed if incise drapes are used, apply directly to dry prep. On completion of surgical procedure, removal of incise drape will remove film. apply dressing following standard practices 	
Other information • store between 20-25°C (68-77°F) • avoid excessive heat above 40°C (104°F) • solution is not water soluble and may stain. Therefore, avoid contact with reusable items (linens, instruments).	
Inactive ingredients ethyl alcohol, water	
Questions? call 1-800-228-3957 (Monday to Friday 7AM – 6PM CST). www.3M.com	

3M DuraPrep™ Surgical Solution Iodine Povacrylex (0.7% Available Iodine) and Isopropyl Alcohol (74% w/w) Patient Preoperative Skin Preparation Non-sterile Solution Applicator is sterile if package is intact For large prep areas below the neck		STERILE EO NDC 17518-011-08 MAL09032040XR Do Not Reuse Not Made With Natural Rubber Latex
WARNING Flammable Keep away from fire or flame. To reduce the risk of fire, PREP CAREFULLY: <ul style="list-style-type: none"> Do not use 26 mL applicator for head and neck surgery. Do not use on an area smaller than 8 in x 10 in; Use a small applicator instead. Solution contains alcohol and gives off flammable vapors. Do not drape or use ignition source (e.g., cautery, laser) until solution is completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Avoid getting solution into hairy areas. Wet hair is flammable. Hair may take up to 1 hour to dry. Do not allow solution to pool. Remove solution-stained material from prep area. 		
Single Use DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.9 fl oz (26 mL) of solution which covers a 15 in x 30 in area (approximately from shoulder to groin in an average size adult). For procedures requiring less coverage, a smaller applicator is available (8635). It contains 0.2 fl oz (6 mL) of solution which covers an approximate 8 in x 10 in area. Do not use more than required for the area. 3M recommends all users participate in product in-service training prior to use. In-service is available on video, from your 3M sales representative, or at the 3M website (www.3M.com).		
REF 8630 0.9 fl oz • 26 mL  (01) 0 03 17518 01108 5 3M Made in U.S.A. by 3M Health Care 2510 Canby Ave. St. Paul, MN 55144 1-800-228-3957 © 2021, 3M. All rights reserved. 3M and DuraPrep are trademarks of 3M. 34-8728-0074-2		
Patient Take Home Instructions Your surgeon used 3M™ DuraPrep™ Surgical Solution 8630, a bacteria-killing skin preparation. It is recommended that this film remain on the skin after the procedure. The film will gradually wear away. If, however, early removal is desired: <ul style="list-style-type: none"> Apply 8610 or 8611 3M™ Remover Lotion to the prepped area keeping away from the wound edge or puncture site. Wipe off with a disposable towel, or Soak gauze with 70% isopropyl alcohol and place on the prepped area for at least 40 seconds. Lightly scrub to remove the solution. If you have questions, call 1-800-228-3957		

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3M DURAPREP SURGICAL

iodine povacrylex and isopropyl alcohol solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17518-011
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Iodine Povacrylex (UNII: 6E43AWY083) (Iodine - UNII:9679TC07X4)	Iodine	6.02 mg in 1 mL

Isopropyl Alcohol (UNII: ND2M416302) (Isopropyl Alcohol - UNII:ND2M416302)	Isopropyl Alcohol	636.4 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
Alcohol (UNII: 3K9958V90M)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-011-08	1 in 1 CASE	09/29/2006	
1		26 mL in 1 APPLICATOR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021586	09/29/2006	

Labeler - Solventum US OpCo LLC (006173082)

Establishment

Name	Address	ID/FEI	Business Operations
3M Company		054950670	ANALYSIS(17518-011) , PACK(17518-011)

Establishment

Name	Address	ID/FEI	Business Operations
3M Company		078671244	MANUFACTURE(17518-011)

Establishment

Name	Address	ID/FEI	Business Operations
3M Company		830016148	ANALYSIS(17518-011)