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:

- 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:
- grasp product by wrapping hand and fingers around the labeled portion of the applicator. Place thumb on the lever.
- with sponge face parallel to the floor, snap lever. Allow all fluid to flow into sponge.

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.
- 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 20-25ºC (68-77ºF)
- avoid excessive heat above 40ºC (104ºF)
- 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 – 6 mL Applicator Label

3M

STERILE EO

NDC 17518-011-07

Do Not Reuse

1. SNAP

2. PAINT, DO

NOT SCRUB

DuraPrep TM

Surgical Solution

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

Patient Preoperative Skin Preparation **For head, neck, and small prep areas**

Non-sterile Solution Applicator is sterile if package is intact

REF 8635 0.2 fl oz • 6 mL

External Use Only Professional Use Only

Read Drug Facts Information before use.

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

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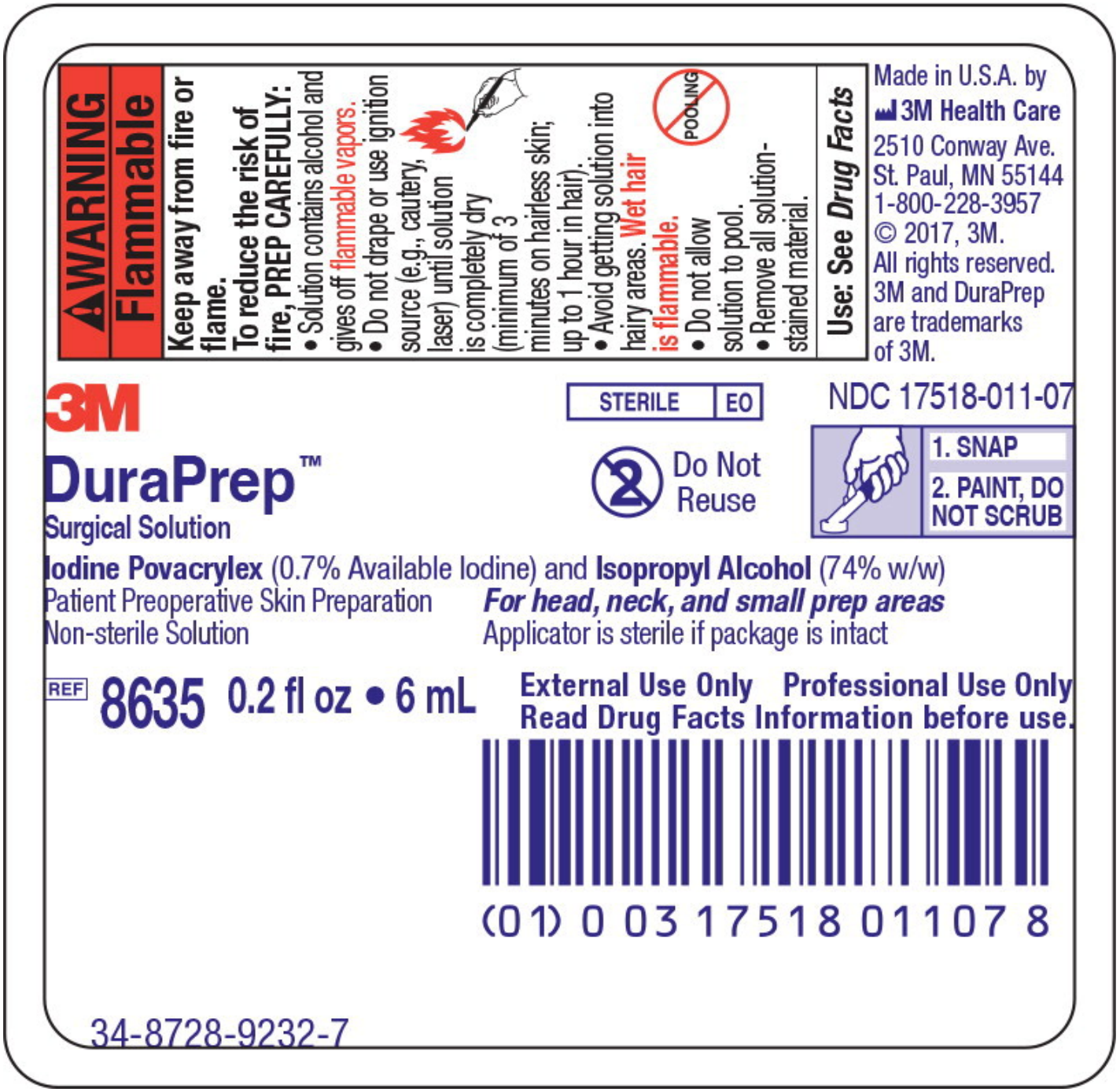

Principal Display Panel – 6 mL Insert Label

3M

STERILE EO

NDC 17518-011-07

MAL09032040XR

DuraPrep TM

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 head, neck, and small prep areas

Latex-Free

Not Made With Natural Latex

Do Not Reuse

Single Use

DuraPrep Surgical Solution is a film-forming iodophor complex. Each unit dose applicator contains 0.2 fl oz (6 mL) of solution which covers an approximate 8 in x 10 in 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 8635 0.2 fl oz • 6 mL

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3M Health Care

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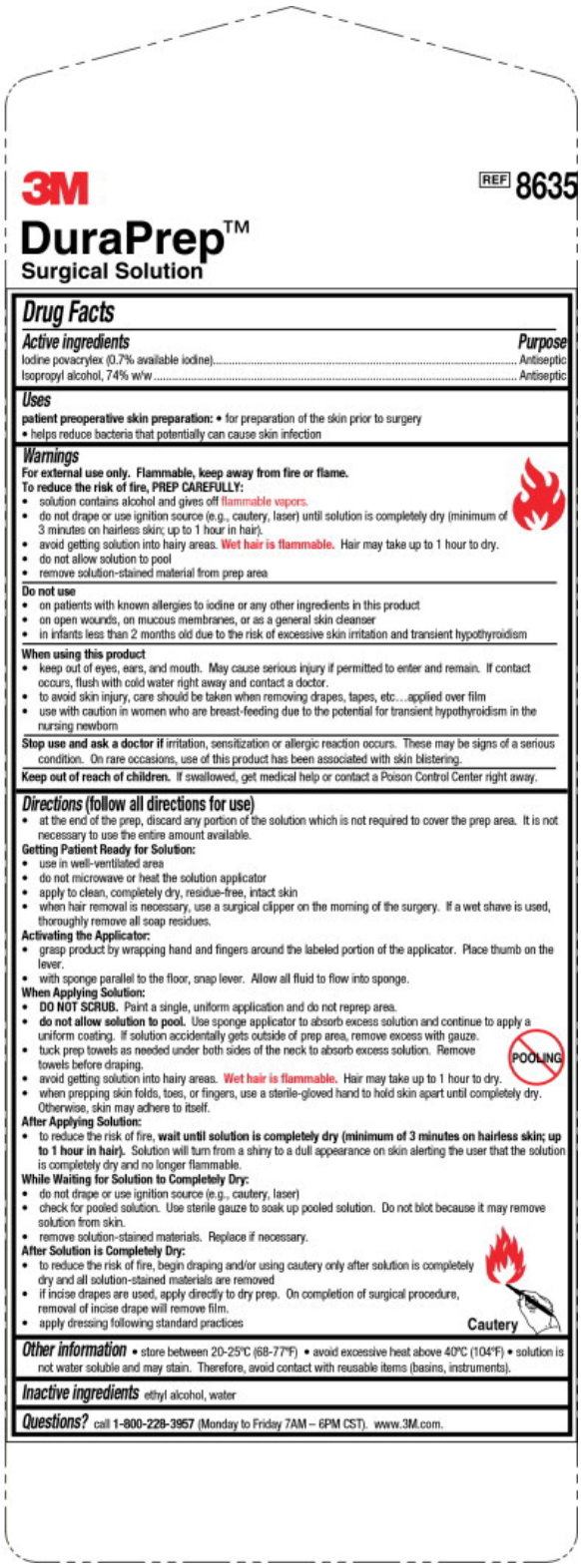
St. Paul, MN 55144

1-800-228-3957



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

Inactive Ingredients

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17518-011-07	1 in 1 CASE	09/29/2006	
1		6 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)