

**PROFEND NASAL DECOLONIZATION- povidone iodine usp, 10% w/w swab**  
**Professional Disposables International, Inc.**

*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.*

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**Profend Nasal Decolonization Kit**

**Active Ingredient**

Povidone-Iodine USP 10% w/w (equivalent to 1.0% titratable iodine)

**Purpose**

Antiseptic

**Uses**

- Antiseptic for preparation of skin
- Helps reduce bacteria that can potentially cause skin infection
- A broad spectrum antiseptic for topical application for preparation of skin prior to surgery

**Warnings**

**For external use only**

**Do not use**

- in the eyes or mouth
- on individuals who are allergic or sensitive to iodine
- over large areas of the body

**Stop use and ask doctor if** irritation and redness develop or if condition persists for more than 72 hours.

**Ask a doctor before use if you have**

- Deep or puncture wounds
- animal bites
- serious burns

**Keep out of reach of children.**

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

**Directions**

For nasal application:

Step 1: Use tissue to clean inside of both nostrils, including inside tips of nostrils. Discard tissue.

Using total of four swabsticks, perform Steps 2-6 two times for right nostril and two times for left nostril.

Step 2: Hold applicator tube between thumb and forefinger at blue band with tube in vertical position with tip/handle up. With the other hand, place thumb and forefinger at base of handle (“thumb-to-thumb”).

Step 3: Bend and snap open along break line.

Step 4: Bend and snap in opposite direction to disconnect swabstick.

Step 5: Remove swabstick from tube. Discard tube.

Step 6: Insert swabstick comfortably into one nostril. For a total of 15 seconds, rotate swabstick around circumference of nostril and then rotate in the anterior nares for a minimum of 6 complete revolutions with slight pressure, covering all surfaces. Discard swabstick.

Note: Do not blow nose. If solution drips, gently wipe with a tissue.

#### **Other information**

- For hospital and professional use
- Store at room temperature (15-29 °C; 59-84 °F)
- Avoid excessive heat

#### **Inactive Ingredients**

Purified Water, Sodium Hydroxide

#### **Questions?**

call 1-800-999-6423 (M-F 9 a.m.-5 p.m. EST)

#### **Principal Display Panel**

Profend

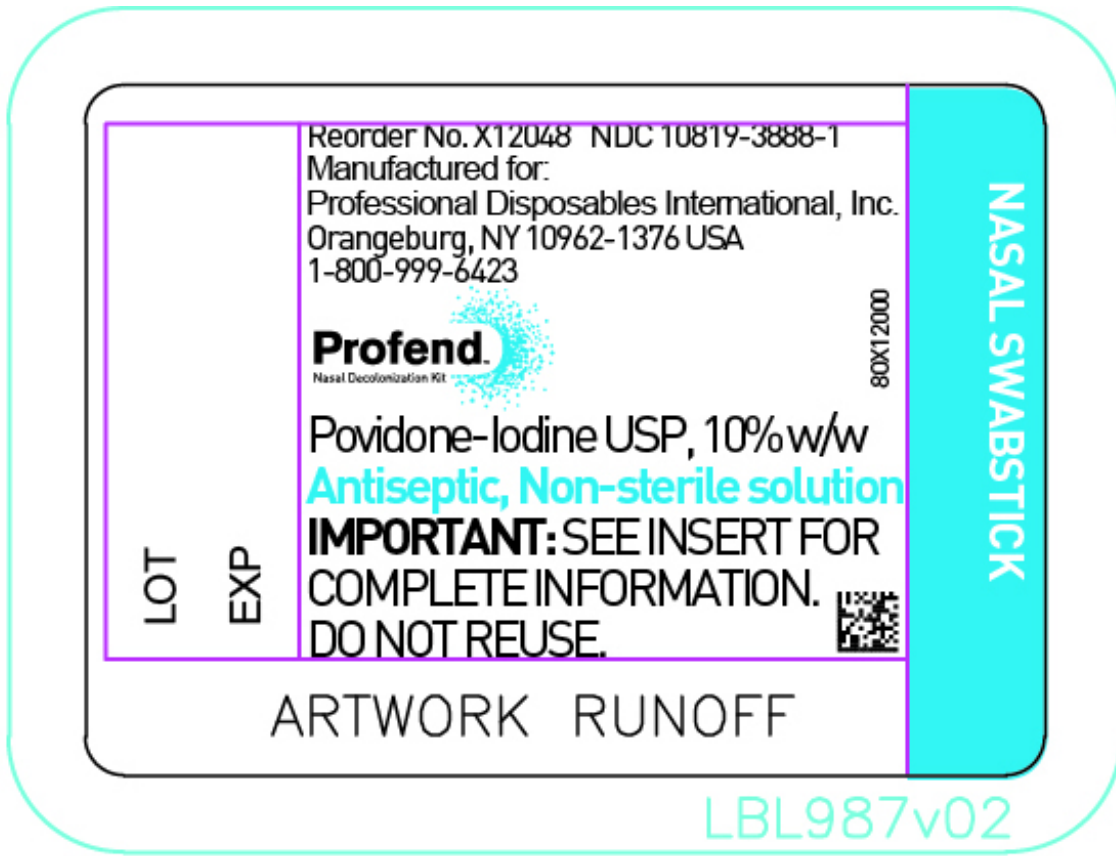
Nasal Decolonization Kit

Povidone-Iodine USP, 10% w/w

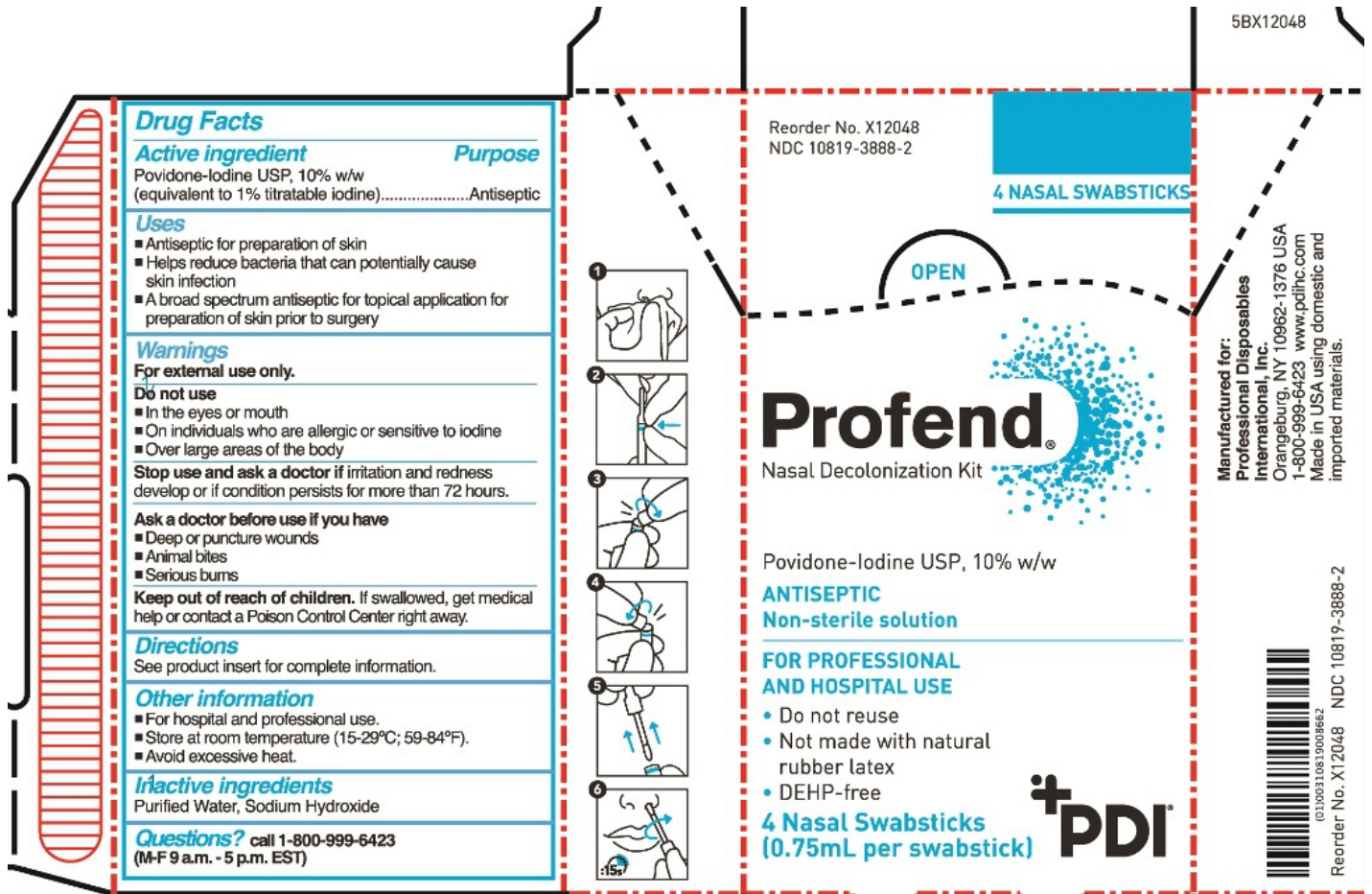
Antiseptic

Non-sterile solution

Swabstick



box



carton



insert

5BX120IN

**Profend® NASAL SWABSTICKS**  
 Reorder No. X12048 NDC 10819-3888-1

Drug Facts	Purpose
<p><b>Active ingredient</b> Povidone-iodine USP, 10% w/w (equivalent to 1% titratable iodine).....Antiseptic</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ Antiseptic for preparation of skin</li> <li>■ Helps reduce bacteria that can potentially cause skin infection</li> <li>■ A broad spectrum antiseptic for topical application for preparation of skin prior to surgery</li> </ul> <p><b>Warnings</b></p> <p><b>For external use only.</b></p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ In the eyes or mouth</li> <li>■ On individuals who are allergic or sensitive to iodine</li> <li>■ Over large areas of the body</li> </ul> <p><b>Stop use and ask doctor</b> if irritation and redness develop or if condition persists for more than 72 hours.</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ Deep or puncture wounds</li> <li>■ Animal bites</li> <li>■ Serious burns</li> </ul> <p><b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away. ▶</p>	

**Drug Facts (continued)**

**Directions**  
 For nasal application:

- **Step 1:** Use tissue to clean inside of both nostrils, including inside tips of nostrils. Discard tissue. Using total of four swabsticks, perform Steps 2-6 two times for right nostril and two times for left nostril.
- **Step 2:** Hold applicator tube between thumb and forefinger at blue band with tube in vertical position with tip/handle up. With the other hand, place thumb and forefinger at base of handle ("thumb-to-thumb").
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**Other information**

- For hospital and professional use.
- Store at room temperature (15-29°C; 59-84°F).
- Avoid excessive heat.

**Inactive ingredients**  
 Purified Water, Sodium Hydroxide

**Questions? call 1-800-999-6423 (M-F 9 a.m.- 5 p.m. EST)**

## PROFEND NASAL DECOLONIZATION

povidone iodine usp, 10% w/w swab

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10819-3888
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	10 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10819-3888-3	12 in 1 CARTON	02/16/2018	
1	NDC:10819-3888-2	4 in 1 BOX		
1		0.75 mL in 1 TUBE, WITH APPLICATOR; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/16/2018	

**Labeler** - Professional Disposables International, Inc. (800777117)**Establishment**

Name	Address	ID/FEI	Business Operations
Professional Disposables International, Inc.		800777117	manufacture(10819-3888)

Revised: 11/2019

Professional Disposables International, Inc.