

**SWAB APPLICATOR BRUSHE7.5% W/W POVIDONE-IODINE (PVP)- povidone-iodine swab**  
**XINXIANG XINDA TECHNOLOGY CO.,LTD**

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**84128-007**

***Active ingredients***

Povidone-Iodine 7.5% w/w

***Purposes***

Antiseptic

***Use***

for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

***Warnings***

**For external use only.**

**PREP CAREFULLY:**

Do not use 3-ml applicator for head and neck surgery  
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)  
Do not allow solution to pool  
Remove wet materials from prep area

**Do not use**

On patients with known allergies to chlorhexidine gluconate or isopropyl alcohol  
For lumbar puncture or in contact with the meninges  
On open skin wounds or as a general skin cleanser

**When using this product**

keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

**Stop use and ask a doctor**

if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

**Keep out of reach of children.**

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

### **Directions**

Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

Use in a well ventilated area

Maximal treatment area for one applicator is approximately 4 in. x 5 in. (129 cm<sup>2</sup>).

Do not use 3-ml applicator for head and neck surgery

Remove applicator from package; do not touch sponge hold the applicator with the sponge down. Open the switch only once to activate the ampules and release the antiseptic.

Wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin

Completely wet the treatment area with antiseptic

Dry surgical sites(e.g. abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds

Moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes

Do not allow solution to pool; tuck prep towels to absorb solution, and then remove  
Allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.

Discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

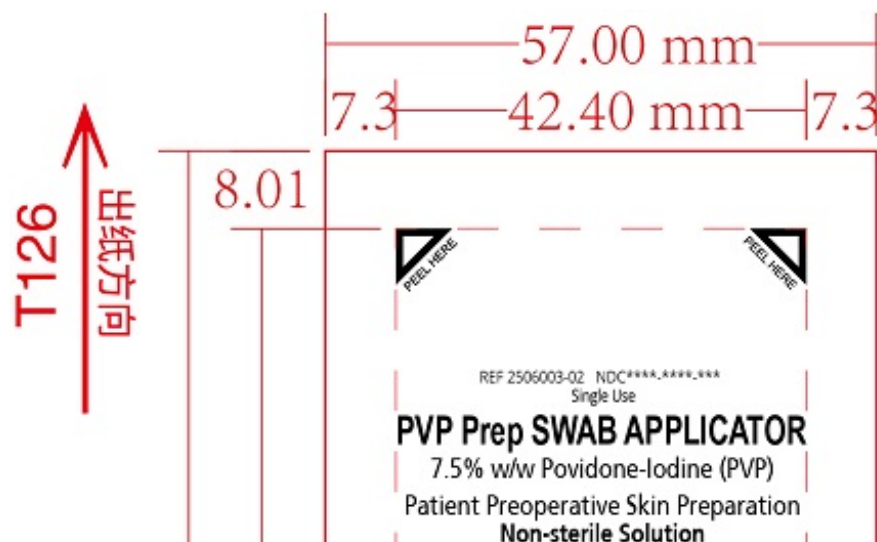
### **Other information**

Store between 15-30°C (59-86°F) avoid freezing and excessive heat above 40°C(104°F)

### **Inactive ingredients**

Purified water

### **84128-007-03**



200.03 mm  
184.00 mm

Applicator is sterile if package is intact

### 3 ml APPLICATOR

#### Drug Facts

**Active ingredients**                      **Purposes**  
Povidone-iodine 7.5% w/v ..... Antiseptic

**Use** for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

#### Warnings

For external use only.

#### PREP CAREFULLY:

- Do not use 3-ml applicator for head and neck surgery
- 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)
- Do not allow solution to pool
- Remove wet materials from prep area

#### Do not use

- On patients with known allergies to Povidone-iodine
- For lumbar puncture or in contact with the meninges
- On open skin wounds or as a general skin cleanser

**When using this product** keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

**Stop use and ask a doctor if** irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

#### Directions

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation
- Use in a well ventilated area
- Maximal treatment area for one applicator is approximately 4 in. x 5 in. (129 cm<sup>2</sup>).
- Do not use 3-ml applicator for head and neck surgery
- Remove applicator from package; do not touch sponge hold the applicator with the sponge down. Open the switch only once to activate the ampules and release the antiseptic.
- Wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
- Completely wet the treatment area with antiseptic
- Dry surgical sites (e.g. abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds
- Moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
- Do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- Allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- Discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

#### Other information

Store between 15-30°C (59-86°F)  
avoid freezing and excessive heat above 40°C(104°F)

#### Inactive ingredients

Purified water

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8.01

客户	新乡新达		品牌	
设计	WY	产品名称	REF 2506003-02	成品尺寸 57x200.03mm
校对		客户文件图号		印刷尺寸 42.4x184mm
审核		译源文件图号	QZ-XD251230-6	颜色:黑色
质量		备注		
工艺				

T126

出纸方向



6.31

200.03 mm

187.40 mm

57.00 mm

7.3

42.40 mm

7.3



REF 2506006-02 NDC\*\*\*\*.\*\*\*\*.\*\*\*  
Single Use

# PVP Prep SWAB APPLICATOR

7.5% w/w Povidone-Iodine (PVP)

Patient Preoperative Skin Preparation

**Non-sterile Solution**

Applicator is sterile if package is intact

**6 ml APPLICATOR**

## Drug Facts

### Active ingredients

### Purposes

Povidone-Iodine 7.5% w/w ..... Antiseptic

**Use** for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

### Warnings

**For external use only.**

#### PREP CAREFULLY:

- Do not use 6-ml applicator for head and neck surgery
- 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)
- Do not allow solution to pool
- Remove wet materials from prep area

#### Do not use

- On patients with known allergies to Povidone-Iodine
- For lumbar puncture or in contact with the meninges
- On open skin wounds or as a general skin cleanser

**When using this product** keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

**Stop use and ask a doctor if** irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

### Directions

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation
- Use in a well ventilated area
- Maximal treatment area for one applicator is approximately 5 in. x 8 in. (260 cm<sup>2</sup>). Do not use 6-ml applicator for area smaller than 4 in. x 5 in. Use a smaller applicator instead.
- Do not use 6-ml applicator for head and neck surgery
- Remove applicator from package; do not touch sponge hold the applicator with the sponge down. Open the switch only once to activate the ampules and release the antiseptic.
- Wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
- Completely wet the treatment area with antiseptic
- Dry surgical sites(e.g. abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds
- Moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
- Do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- Allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- Discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

**Other information**

Store between 15-30°C (59-86°F)  
avoid freezing and excessive heat above 40°C(104°F)

**Inactive ingredients**

Purified water

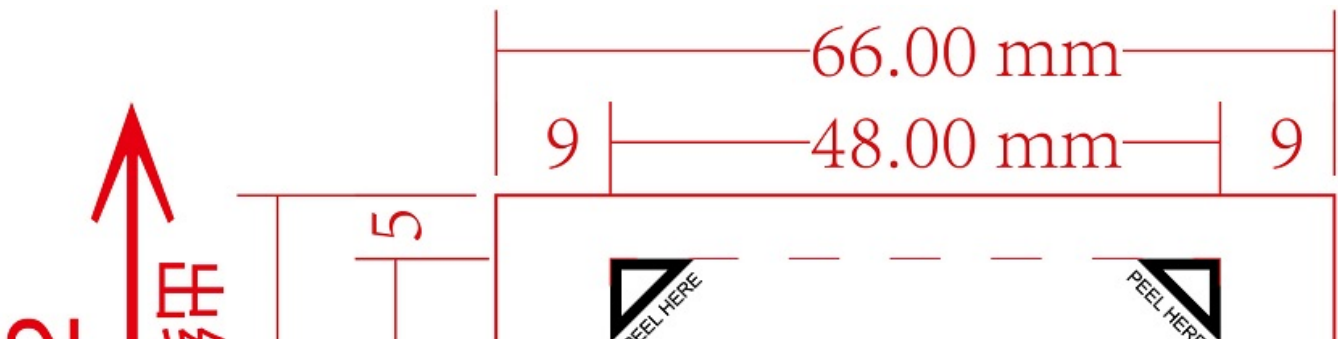
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6.31

客 户	新乡新达		品 牌	
设 计	WY	产品名称	REF 2506006-02	成品尺寸 57x200.03mm
校 对		客户文件图号		印刷尺寸 42.4x187.4mm
审 核		泽潇文件图号	QZ-XD260105-3	颜 色 :黑色
质 量		备 注		
工 艺				

84128-007-10



T72

纸方向

228.60 mm

215.00 mm

5

8

REF 2506105-02 NDC\*\*\*\*\_\*\*\*\*\_\*\*\*

Single Use

# PVP Prep SWAB APPLICATOR

7.5% w/w Povidone-Iodine (PVP)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

## 10.5 ml APPLICATOR

### Drug Facts

Active ingredients	Purposes
Povidone-Iodine 7.5% w/w	Antiseptic

**Use** for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

#### Warnings

For external use only.

##### PREP CAREFULLY:

- Do not use 10.5-ml applicator for head and neck surgery
- Do not use on an area smaller than 5 in. x 8 in. Use a smaller applicator instead.
- 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)
- Do not allow solution to pool
- Remove wet materials from prep area

##### Do not use

- On patients with known allergies to Povidone-Iodine
- For lumbar puncture or in contact with the meninges
- On open skin wounds or as a general skin cleanser

**When using this product** keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

**Stop use and ask a doctor** if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

#### Directions

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation
- Use in a well ventilated area
- Maximal treatment area for one applicator is approximately 8.4 in. x 8.4 in. (455 cm<sup>2</sup>). Do not use 10.5-ml applicator for area smaller than 5 in. x 8 in. Use a smaller applicator instead.
- Do not use 10.5-ml applicator for head and neck surgery
- Remove applicator from package; do not touch sponge hold the applicator with the sponge down. Open the switch only once to activate the ampules and release the antiseptic.
- Wet the sponge by pressing and releasing the

8.6

sponge against the treatment area until liquid is visible on the skin

- Completely wet the treatment area with antiseptic
- Dry surgical sites(e.g, abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds
- Moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
- Do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- Allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- Discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.


**Other information**

Store between 15-30°C (59-86°F)  
avoid freezing and excessive heat above 40°C(104°F)

**Inactive ingredients**

Purified water

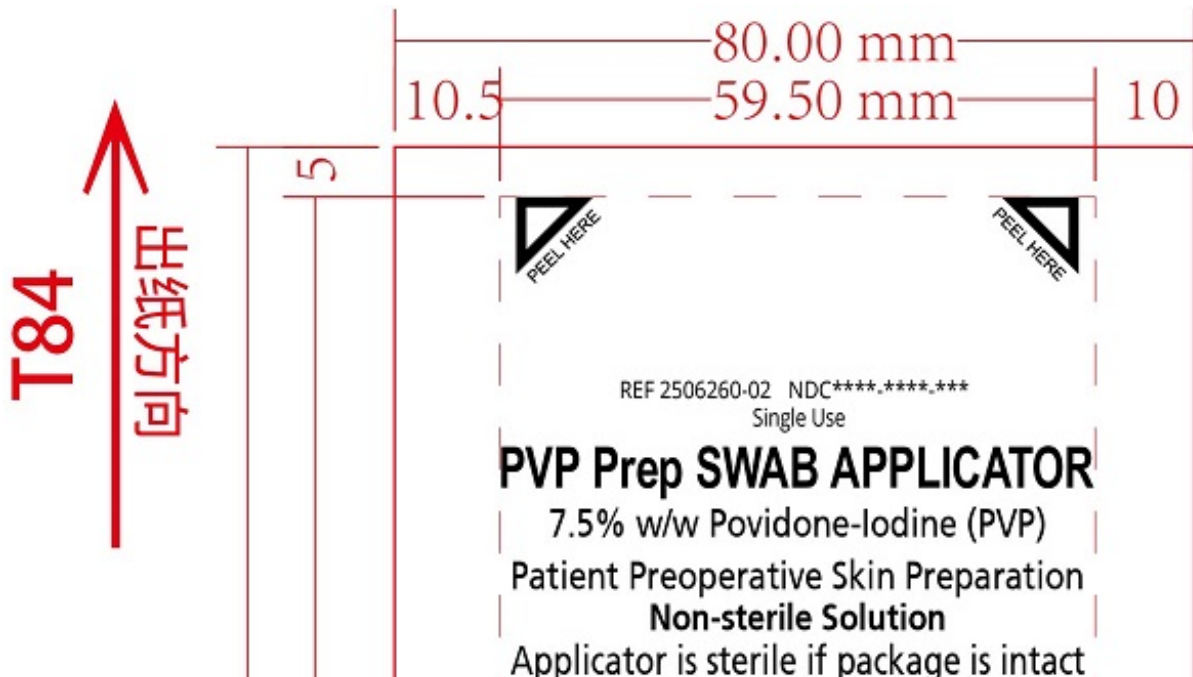
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6 977191 590204

客 户	新乡新达	品 牌		
设 计	WY	产品名称	REF 2506105-02	成品尺寸 66x228.6mm
校 对		客户文件图号		印刷尺寸 48x215mm
审 核		泽潇文件图号	QZ-XD251230-3	颜 色 :黑色
质 量		备 注		
工 艺				

**84128-007-26**



# 26 ml APPLICATOR

266.70 mm  
251.50 mm

## Drug Facts

Active ingredients	Purposes
Povidone-Iodine 7.5% w/w	Antiseptic

**Use** for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

### Warnings

For external use only.

#### PREP CAREFULLY:

- Do not use 26-ml applicator for head and neck surgery
- Do not use on an area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.
- 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)
- Do not allow solution to pool
- Remove wet materials from prep area

#### Do not use

- On patients with known allergies to Povidone-Iodine
- For lumbar puncture or in contact with the meninges
- On open skin wounds or as a general skin cleanser

**When using this product** keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

**Stop use and ask a doctor** if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

### Directions

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation
- Use in a well ventilated area
- Maximal treatment area for one applicator is approximately 13.2 in. x 13.2 in. (1126 cm<sup>2</sup>). Do not use 26-ml applicator for area smaller than 8.4 in. x 8.4 in. Use a smaller applicator instead.
- Do not use 26-ml applicator for head and neck surgery
- Remove applicator from package; do not touch sponge hold the applicator with the sponge down. Open the switch only once to activate the ampules and release the antiseptic.
- Wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
- Completely wet the treatment area with antiseptic
- Dry surgical sites(e.g, abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds
- Moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
- Do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- Allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- Discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

### Other information

Store between 15-30°C (59-86°F)  
avoid freezing and excessive heat above 40°C(104°F)

### Inactive ingredients

USP purified water

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10.2

客户	新乡新达		品牌		
设计	YLJ	产品名称	26ML PVP - 02	成品尺寸	80x266.7mm
校对		客户文件图号		印刷尺寸	59.5x251.5mm
审核		译满文件图号	QZ-XD251011-2	颜色	黑色
质量		备注	131003-1011		
工艺					

84128-007-30

T84  
 ↑  
 出纸方向

80.00 mm  
 59.50 mm  
 10.5  
 10  
 5

PEEL HERE

REF 2506300-02 NDC\*\*\*\*,\*\*\*\*,\*\*\*  
 Single Use

**PVP Prep SWAB APPLICATOR**  
 7.5% w/w Povidone-Iodine (PVP)  
 Patient Preoperative Skin Preparation  
**Non-sterile Solution**  
 Applicator is sterile if package is intact  
**30 ml APPLICATOR**

**Drug Facts**

Active ingredients	Purposes
Povidone-Iodine 7.5% w/w	Antiseptic

**Use** for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

**Warnings**  
 For external use only.  
**PREP CAREFULLY:**

- Do not use 30-ml applicator for head and neck surgery
- Do not use on an area smaller than 132 in. x 132 in. Use a smaller applicator instead.
- 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)
- Do not allow solution to pool
- Remove wet materials from prep area

Do not use

70 mm  
 50 mm

266.7  
251.5

- On patients with known allergies to Povidone-Iodine
- For lumbar puncture or in contact with the meninges
- On open skin wounds or as a general skin cleanser

**When using this product** keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

**Stop use and ask a doctor** if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

**Directions**

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation
- Use in a well ventilated area
- Maximal treatment area for one applicator is approximately 14.2 in. x 14.2 in. (1300 cm<sup>2</sup>). Do not use 30-ml applicator for area smaller than 13.2 in. x 13.2 in. Use a smaller applicator instead.
- Do not use 30-ml applicator for head and neck surgery
- Remove applicator from package; do not touch sponge hold the applicator with the sponge down. Open the switch only once to activate the ampules and release the antiseptic.
- Wet the sponge by pressing and releasing the sponge against the treatment area until liquid is visible on the skin
- Completely wet the treatment area with antiseptic
- Dry surgical sites(e.g, abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds
- Moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
- Do not allow solution to pool; tuck prep towels to absorb solution, and then remove
- Allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
- Discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

**Other information**

Store between 15-30°C (59-86°F)  
avoid freezing and excessive heat above 40°C(104°F)

**Inactive ingredients**

USP purified water

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10.2

客户	新乡新达		品牌		
设计	YLJ	产品名称	26ML PVP - 02	成品尺寸	80x266.7mm
校对		客户文件图号		印刷尺寸	59.5x251.5mm
审核		译满文件图号	QZ-XD251011-2	颜色	黑色
质量		备注	131003-1011		
工艺					

84128-007-35



T84

出纸方向



5

266.70 mm

251.50 mm

PEEL HERE

PEEL HERE

REF 2506350-02 NDC\*\*\*\*,\*\*\*\*,\*\*\*

Single Use

# PVP Prep SWAB APPLICATOR

7.5% w/w Povidone-Iodine (PVP)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

## 35 ml APPLICATOR

### Drug Facts

Active ingredients	Purposes
Povidone-iodine 7.5% w/w	Antiseptic

**Use** for the preparation of the patient's skin prior to surgery. Helps to reduce bacteria that potentially can cause skin infection.

#### Warnings

For external use only.

##### PREP CAREFULLY:

- Do not use 35-ml applicator for head and neck surgery
- Do not use on an area smaller than 14.2 in. x 14.2 in. Use a smaller applicator instead.
- 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)
- Do not allow solution to pool
- Remove wet materials from prep area

##### Do not use

- On patients with known allergies to Povidone-iodine
- For lumbar puncture or in contact with the meninges
- On open skin wounds or as a general skin cleanser

**When using this product** keep out of eyes, ears, and mouth. May cause serious or permanent injury if permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.

**Stop use and ask a doctor** if irritation, sensitization, or allergic reaction occurs. These may be signs of a serious condition.

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

#### Directions

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation
- Use in a well ventilated area
- Maximal treatment area for one applicator is approximately 15.4 in. x 15.4 in. (1520 cm<sup>2</sup>). Do not use 35-ml applicator for area smaller than 14.2 in. x 14.2 in. Use a smaller applicator instead.
- Do not use 35-ml applicator for head and neck surgery
- Remove applicator from package; do not touch sponge hold the applicator with the sponge down. Open the switch only once to activate the ampules and release the antiseptic.
- Wet the sponge by pressing and releasing the

10.2

- sponge against the treatment area until liquid is visible on the skin
- Completely wet the treatment area with antiseptic
  - Dry surgical sites(e.g, abdomen or arm): use gentle repeated back-and-forth strokes for 30 seconds
  - Moist surgical sites (e.g., inguinal fold): use gentle repeated back-and-forth strokes for 2 minutes
  - Do not allow solution to pool; tuck prep towels to absorb solution, and then remove
  - Allow the solution to completely dry (minimum of 3 minutes on hairless skin; up to 1 hour in hair). Do not blot or wipe away.
  - Discard the applicator after a single use along with any portion of the solution not required to cover the prep area. It is not necessary to use the entire amount available.

**Other information**

Store between 15-30°C (59-86°F)  
avoid freezing and excessive heat above 40°C(104°F)

**Inactive ingredients**

USP purified water

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Made In China



客户	新乡新达		品牌	
设计	YLJ	产品名称	26ML PVP - 02	成品尺寸 80x266.7mm
校对		客户文件图号		印刷尺寸 59.5x251.5mm
审核		译满文件图号	QZ-XD251011-2	颜色:黑色
质量		备注	131003-1011	
工艺				

**SWAB APPLICATOR BRUSHE7.5% W/W POVIDONE-IODINE (PVP)**

povidone-iodine swab

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:84128-007
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84128-007-03	20 in 1 BOX	05/13/2026	
1		1 in 1 BAG		
1		3 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
2	NDC:84128-007-06	20 in 1 BOX	05/13/2026	
2		1 in 1 BAG		
2		6 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
3	NDC:84128-007-10	10 in 1 BOX	05/13/2026	
3		1 in 1 BAG		
3		10.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
4	NDC:84128-007-26	10 in 1 BOX	05/13/2026	
4		1 in 1 BAG		
4		26 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
5	NDC:84128-007-30	10 in 1 BOX	05/13/2026	
5		1 in 1 BAG		
5		30 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
6	NDC:84128-007-35	10 in 1 BOX	05/13/2026	
6		1 in 1 BAG		
6		35 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
OTC Monograph Drug	M003	05/13/2026	

**Labeler** - XINXIANG XINDA TECHNOLOGY CO.,LTD (546423962)

## Establishment

Name	Address	ID/FEI	Business Operations
Xinxiang Xinda Technology Co., Ltd.		546423962	manufacture(84128-007)

Revised: 5/2026

XINXIANG XINDA TECHNOLOGY CO.,LTD