

**SWAB APPLICATOR BRUSHES 4% W/W CHLORHEXIDINE GLUCONATE (CHG)-
chlorhexidine gluconate swab
XINXIANG XINDA TECHNOLOGY CO.,LTD**

84128-006

Active ingredients

Chlorhexidine gluconate 4% 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 cm²).

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.

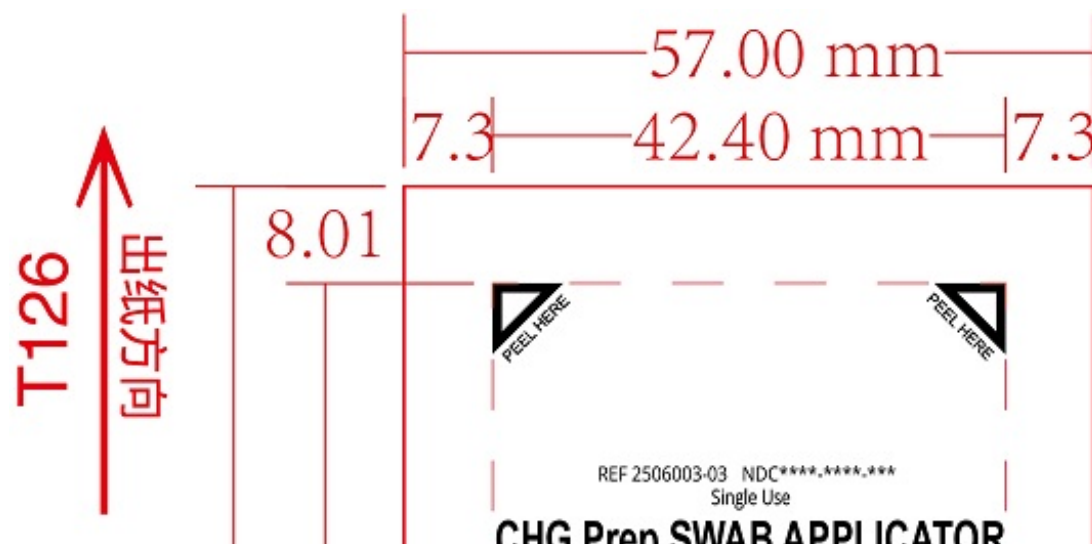
Other information

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

Inactive ingredients

Purified water

84128-006-03



200.03 mm

184.00 mm

ONE STEP SWAB APPLICATION
4% w/w chlorhexidine gluconate (CHG)
Patient Preoperative Skin Preparation
Non-sterile Solution
Applicator is sterile if package is intact
3 ml APPLICATOR

Drug Facts

Active ingredients**Purposes**

Chlorhexidine gluconate 4% w/wAntiseptic

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
- 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 cm²).
- 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

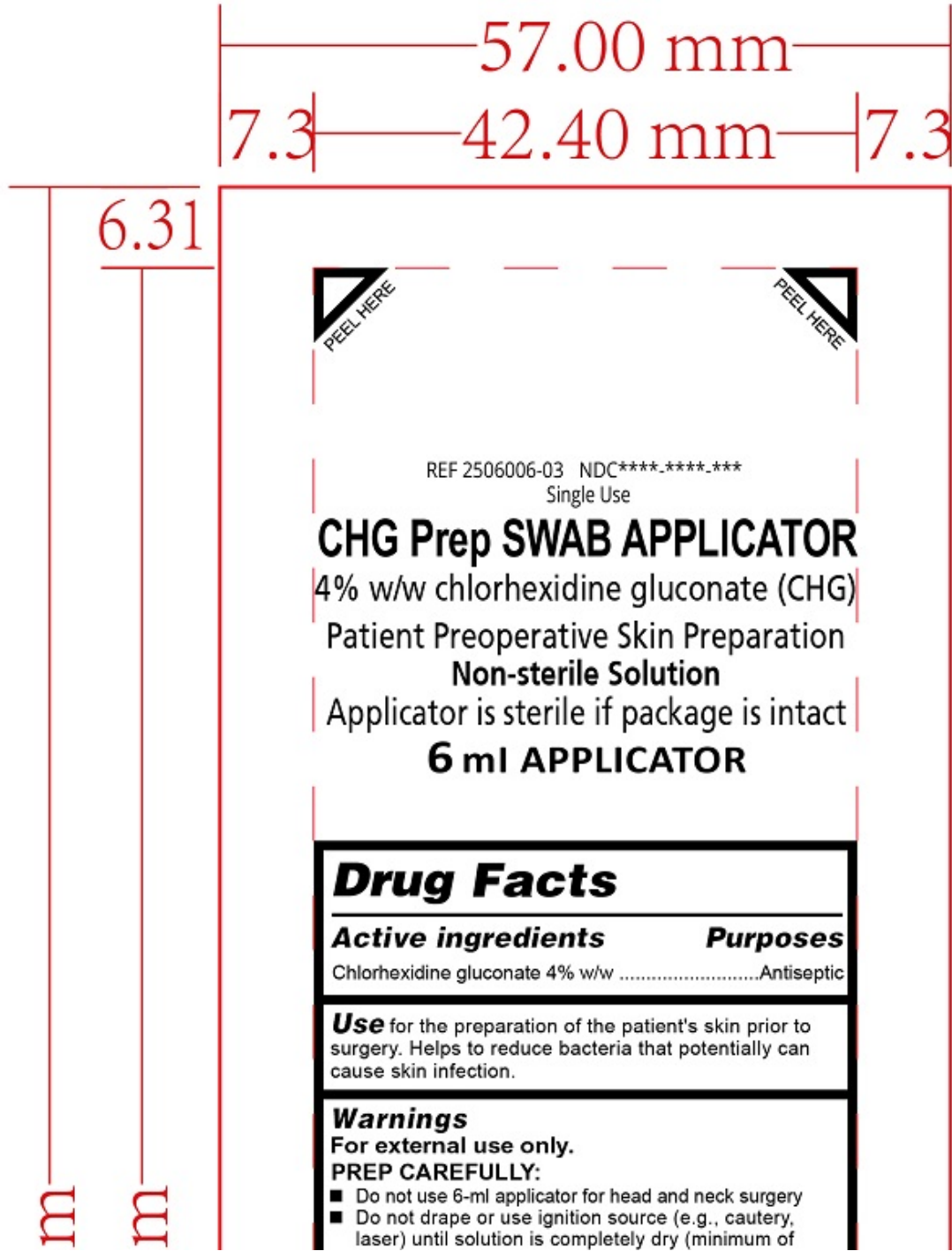


8.01

客户	新乡新达		品牌	
设计	WY	产品名称	REF 2506003-03	成品尺寸 57x200.03mm
校对		客户文件图号		印刷尺寸 42.4x184mm
审核		译稿文件图号	OZ-XD251230-5	颜色:黑色
质量		备注		
工艺				

84128-006-06

T126
↑
出纸方向



200.03 m

187.40 m

6.31

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
- 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 cm²). 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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客户	新乡新达		品牌	
设计	WY	产品名称	REF 2506006-03	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-XD260105-2	颜色:黑色

质量		备注	
工艺			

84128-006-10

T72
出纸方向

66.00 mm
48.00 mm
9 9

5

228.60 mm
215.00 mm

5 8

PEEL HERE PEEL HERE

REF 2506105-03 NDC****.****.***
Single Use

CHG Prep SWAB APPLICATOR
4% w/w chlorhexidine gluconate (CHG)
Patient Preoperative Skin Preparation
Non-sterile Solution
Applicator is sterile if package is intact
10.5 ml APPLICATOR

Drug Facts

Active ingredients	Purposes
Chlorhexidine gluconate 4% 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 Chlorhexidine gluconate
- 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 cm²). 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 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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9.8

客户	新乡新达	品牌			
设计	WY	产品名称	REF 2506105-03	成品尺寸	66x228.6mm
校对		客户文件图号		印刷尺寸	48x215mm
审核		泽瀚文件图号	QZ-XD251230-2	颜色	黑色
质量		备注			
工艺					

84128-006-26



T84

出纸方向



10.5 59.50 mm 10

5

PEEL HERE PEEL HERE

REF 2506260-03 NDC*****.*****.***
Single Use

CHG Prep SWAB APPLICATOR
4% w/w chlorhexidine gluconate (CHG)
Patient Preoperative Skin Preparation
Non-sterile Solution
Applicator is sterile if package is intact
26 ml APPLICATOR

266.70 mm
251.50 mm

Drug Facts

Active ingredients	Purposes
Chlorhexidine gluconate 4% 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 Chlorhexidine gluconate
- 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 cm²). 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

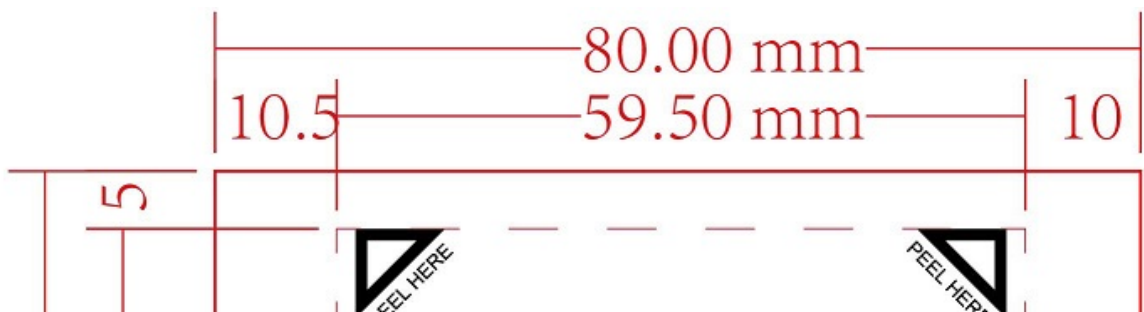
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10.2

客户	新乡新达		品牌	
设计	YLJ	产品名称	26ML CHG - 03	成品尺寸 80x266.7mm
校对		客户文件图号		印刷尺寸 59.5x251.5mm
审核		泽满文件图号	QZ-XD251011-1	颜色:黑色
质量		备注	131002-1011	
工艺				

84128-006-30



T84

纸方向

266.70 mm

251.50 mm

REF 2506300-03 NDC****.****.***

Single Use

CHG Prep SWAB APPLICATOR

4% w/w chlorhexidine gluconate (CHG)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

30 ml APPLICATOR

Drug Facts

Active ingredients

Purposes

Chlorhexidine gluconate 4% w/wAntiseptic

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

- On patients with known allergies to Chlorhexidine gluconate
- 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 cm²). 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

10.2

- 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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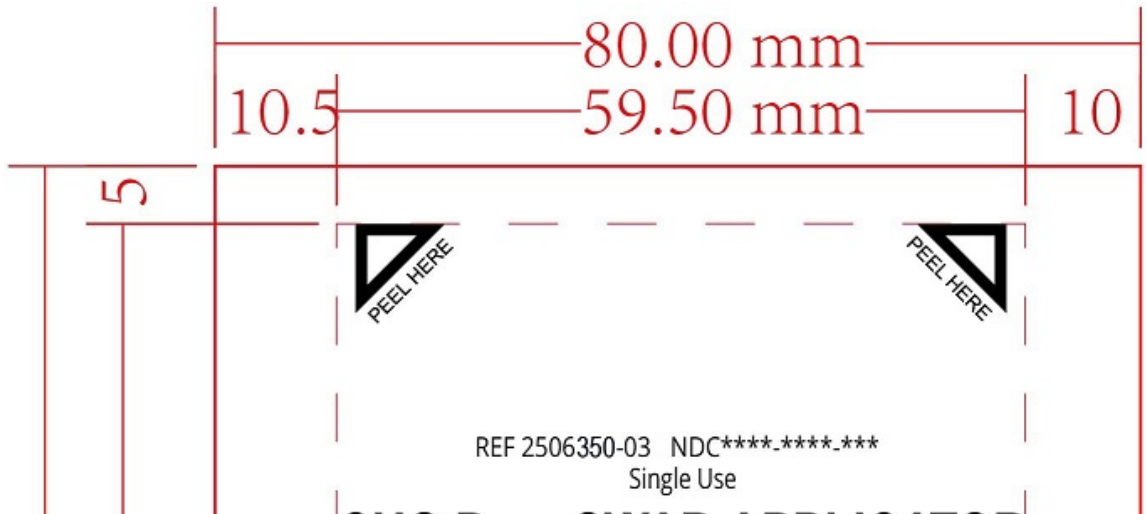


客户	新乡新达		品牌	
设计	YLJ	产品名称	26ML CHG - 03	成品尺寸 80x266.7mm
校对		客户文件图号		印刷尺寸 59.5x251.5mm
审核		泽满文件图号	QZ-XD251011-1	颜色:黑色
质量		备注	131002-1011	
工艺				

84128-006-35

T84

出纸方向



CHG Prep SWAB APPLICATOR

4% w/w chlorhexidine gluconate (CHG)

Patient Preoperative Skin Preparation

Non-sterile Solution

Applicator is sterile if package is intact

35 ml APPLICATOR

266.70 mm

251.50 mm

Drug Facts

Active ingredients

Purposes

Chlorhexidine gluconate 4% w/wAntiseptic

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 Chlorhexidine gluconate
- 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 cm²). 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 sponge against the treatment area until liquid is visible on the skin
- Completely wet the treatment area with antiseptic

10.2

- 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

Xinxiang Xinda Technology Co.,Ltd
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客户	新乡新达		品牌		
设计	YLJ	产品名称	26ML CHG - 03	成品尺寸	80x266.7mm
校对		客户文件图号		印刷尺寸	59.5x251.5mm
审核		泽满文件图号	QZ-XD251011-1	颜色	黑色
质量		备注	131002-1011		
工艺					

SWAB APPLICATOR BRUSHES 4% W/W CHLORHEXIDINE GLUCONATE (CHG)

chlorhexidine gluconate swab

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84128-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84128-006-03	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:84128-006-05	10 in 1 BOX	05/13/2026	
2		1 in 1 BAG		
2		5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
3	NDC:84128-006-06	20 in 1 BOX	05/13/2026	
3		1 in 1 BAG		
3		6 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
4	NDC:84128-006-10	10 in 1 BOX	05/13/2026	
4		1 in 1 BAG		
4		10.5 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
5	NDC:84128-006-26	10 in 1 BOX	05/13/2026	
5		1 in 1 BAG		
5		26 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
6	NDC:84128-006-30	10 in 1 BOX	05/13/2026	
6		1 in 1 BAG		
6		30 mL in 1 APPLICATOR; Type 0: Not a Combination Product		
7	NDC:84128-006-35	10 in 1 BOX	05/13/2026	
7		1 in 1 BAG		
7		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	505G(a)(3)	05/13/2026	

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

Establishment

Name	Address	ID/FEI	Business Operations
Xinxiang Xinda Technology Co., Ltd.		546423962	manufacture(84128-006)

