

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-524

LABELING

NDA 21-524

Page 4

Chlorascrub Swab Outer Carton Label

“TOP”

NDC 10819-1080-1

REORDER NO. B10800

Chlorascrub™ Swab

[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

Antiseptic

*equivalent to 167 mg of Chlorhexidine Gluconate per pouch

Contains: 100 Individual Swabs,

0.034 fl.oz. (1 mL) Each

PDI®

Made in U.S.A.

PDI, The Healthcare Division of Nice-Pak Products, Inc.

Chlorascrub™ is under license by American Solumed Inc.

Convenience • Comfort • Caring

Chlorascrub Swab Packet Label

“FRONT”

NDC 10819-1080-1

REORDER NO. B10800

Chlorascrub™ Swab

**[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
Antiseptic**

*equivalent to 167 mg of Chlorhexidine Gluconate per pouch

- **For external use only**
- Use for the preparation of the patient's skin prior to an injection
- Helps reduce bacteria that potentially can cause skin infection
- For hospital and professional use only
- Latex free

IMPORTANT: See carton for complete *Drug Facts* and safety information.

One Swab, 0.034 fl.oz. (1 mL) Each

PDI®

Made in U.S.A.

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Chlorascrub Swab Shipping Label

“Label Text”

NET CONTENTS: 10 BOXES OF 100 INDIVIDUAL SWABS
REORDER NO. B10800
NDC the 10819-1080-1

Chlorascrub™ Swab
[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
Antiseptic

*equivalent to 167 mg of Chlorhexidine Gluconate per pouch.

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Chlorhexidine gluconate 3.15% w/v.....	Antiseptic
Isopropyl alcohol 70% v/v.....	Antiseptic

Use for preparation of the patient’s skin prior to an injection

Warnings

For external use only
Flammable, keep away from fire or flame
Do not use with electrocautery procedures

Do not use

- in premature or low birth weight infants or on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- 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
- under occlusive patch

When using this product keep out of eyes, ears mouth and mucous membranes. 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 doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.

NDA 21-524

Page 7

Chlorascrub Swabstick Outer Carton Label

“TOP”

NDC 10819-4075-1

REORDER NO. S40750

Chlorascrub™ Swabstick

[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

Patient preoperative skin preparation

*equivalent to 268 mg of Chlorhexidine Gluconate per pouch

Contains: 50 Individual Swabsticks,

0.054 fl.oz. (1.6 mL) Each

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Chlorascrub Swabstick Packet Label

“FRONT”

NDC 10819-4075-1

REORDER NO. S40750

Chlorascrub™ Swabstick

[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

Patient preoperative skin preparation

*equivalent to 268 mg of Chlorhexidine Gluconate per pouch

■ **For external use only**

■ Use for the preparation of the patient's skin prior to surgery or injection

■ Helps reduce bacteria that potentially can cause skin infection

■ Latex free

■ For hospital and professional use only

IMPORTANT: See carton for complete *Drug Facts* and safety information

One Swabstick, 0.054 fl.oz. (1.6 mL) Each

PDI®

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Chlorascrub Swabstick Shipping Label

“Label Text”

NET CONTENTS: 10 BOXES OF 50 INDIVIDUAL SWABSTICKS
REORDER NO. S40750
NDC 10819-10819-4075-1

Chlorascrub™ Swabstick
[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
Patient preoperative skin preparation
*equivalent to 268 mg of Chlorhexidine Gluconate per pouch

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Chlorhexidine gluconate 3.15% w/v.....	Antiseptic
Isopropyl alcohol 70% v/v.....	Antiseptic

Use for the preparation of the patient’s skin prior to surgery or injection

Warnings

For external use only
Flammable, keep away from fire or flame
Do not use with electrocautery procedures

Do not use

- in premature or low birth weight infants or on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- 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
- under occlusive patch

When using this product keep out of eyes, ears mouth and mucous membranes. 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 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.▶

Drug Facts (continued)

Directions

- **maximum treatment area for one swabstick is approximately: dry site: 4 by 4 inches (10 by 10 cm) or moist site: 3 by 5 inches (7.5 by 12.5 cm)**
- peel apart the pouch to expose the swabstick
- remove the swabstick from package. Do not touch the foam tip.
- prior to surgery or injection, apply swabstick to the procedure site
- place one flat side of foam tip to the proposed skin site and prep the skin in **vigorous** back-and-forth repeated strokes for one (1) minute
- turn the swabstick over (unused side of the foam tip) and repeat the procedure by prepping for one (1) minute
- allow the prepped area to air dry for one and one half minutes (1.5 minutes)
- do not blot or wipe dry
- discard after single use

Other information

- store between 68-77°F (20-25°C)
- avoid freezing and excessive heat above 104°F (40°C)
- for hospital and professional use only

Inactive ingredient

USP purified water

Questions? Call 1-800-999-6423, M-F (9:00 am-5:00 pm EST).

Each swabstick contains 0.054 fl.oz. (1.6 mL)

“Bar Code”

8OS40750

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Chlorascrub Maxi Swabstick Outer Carton Label

“TOP”

NDC 10819-4075-2

REORDER NO. S41950

Chlorascrub™ Maxi Swabstick

[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]

Patient preoperative skin preparation

***equivalent to 855 mg of Chlorhexidine Gluconate per pouch**

Contains: 30 Individual Maxi Swabsticks,

0.172 fl.oz. (5.1 mL) Each

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Convenience • Comfort • Caring

Chlorascrub Maxi Swabstick Packet Label

“FRONT”

NDC 10819-4075-2
REORDER NO. S41950

Chlorascrub™ Maxi Swabstick
[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
Patient preoperative skin preparation
*equivalent to 855 mg of Chlorhexidine Gluconate per pouch

- **For external use only**
- Use for the preparation of the patient's skin prior to surgery or injection
- Helps reduce bacteria that potentially can cause skin infection
- For hospital and professional use only
- Latex free

IMPORTANT: See carton for complete *Drug Facts* and safety information.

One Swabstick, 0.172 fl.oz. (5.1 mL) Each

PDI®
Made in U.S.A.

Convenience • Comfort • Caring

Chlorascrub Maxi Swabstick Shipping Label

“Label Text”

NET CONTENTS: 10 BOXES OF 30 INDIVIDUAL SWABSTICKS
REORDER NO. S41950
NDC 10819-4075-2

Chlorascrub™ Maxi Swabstick
[Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab]
Patient preoperative skin preparation
*equivalent to 855 mg of Chlorhexidine Gluconate per pouch

Drug Facts

<i>Active ingredients</i>	<i>Purpose</i>
Chlorhexidine gluconate 3.15% w/v.....	Antiseptic
Isopropyl alcohol 70% v/v.....	Antiseptic

Use for the preparation of the patient’s skin prior to surgery or injection

Warnings

For external use only

Flammable, keep away from fire or flame

Do not use with electrocautery procedures

Do not use

- in premature or low birth weight infants or on children less than 2 months of age because of the potential for excessive skin irritation and increased drug absorption
- 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
- under occlusive patch

When using this product keep out of eyes, ears, mouth, and mucous membranes. 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 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. ►

Drug Facts (continued)

Directions

- **maximum treatment area for one swabstick is approximately: dry site: 7 by 7 inches (18 by 18 cm) or moist site: 3 by 7.5 inches (7.5 by 19 cm)**
- peel apart the pouch to expose the swabstick
- remove the swabstick from package. Do not touch the foam tip.
- prior to surgery or injection apply swabstick to the procedure site
- place one flat side of foam tip to the proposed skin site and prep the skin in **vigorous** back-and-forth repeated strokes for one (1) minute
- turn the swabstick over (unused side of the foam tip) and repeat the procedure by prepping for one (1) minute
- allow the prepped area to air dry for one and one half minutes (1.5 minutes)
- do not blot or wipe dry
- discard after single use

Other information

- store between 68-77°F (20-25°C)
- avoid freezing and excessive heat above 104°F (40°C)
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Questions? Call 1-800-999-6423, M-F (9:00 am-5:00 pm EST).

Each swabstick contains 0.172 fl.oz. (5.1 mL)

“Bar Code”

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