

HIBICLENS - chlorhexidine gluconate solution
Physicians Total Care, Inc.

HIBICLENS®
(Chlorhexidine Gluconate
solution 4.0% w/v)

Drug Facts

<i>Active ingredient</i>	<i>Purpose</i>
Chlorhexidine gluconate solution 4.0% w/v	Antiseptic

Uses

- antimicrobial skin cleanser helps reduce bacteria that potentially can cause disease
- for skin wound and general skin cleansing
- surgical hand scrub
- personnel hand wash
- preoperative skin preparation

Warnings

For external use only

Do not use

- if you are allergic to chlorhexidine gluconate or any other ingredients in this preparation
- as a patient preoperative skin preparation of the head or face
- in contact with the meninges
- in the genital area
- on wounds that involve more than the superficial layers of skin

When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if placed or kept in the eye during surgical procedures, or may cause deafness when instilled in the middle ear through perforated eardrums.
- if contact occurs in any of these areas, rinse with cold water right away

Stop use and ask a doctor if

- irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. 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

- *skin wound and general skin cleansing.* Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of HIBICLENS necessary to cover the skin or wound area and wash gently. Rinse thoroughly.
- *surgical hand scrub.* Wet hands and forearms with water. Scrub for 3 minutes with about 5mL of

HIBICLENS with a brush. Rinse thoroughly under running water. Repeat. Dry thoroughly.

- *personnel hand wash.* Wet hands with water. Dispense about 5mL of HIBICLENS into cupped hands and wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly.
- *preoperative skin preparation.* Apply HIBICLENS liberally to surgical site and swab for at least 2 minutes. Dry with a sterile towel. Repeat. Dry with a sterile towel.

Other information

store between 20-25°C (68-77°F).

Inactive ingredients

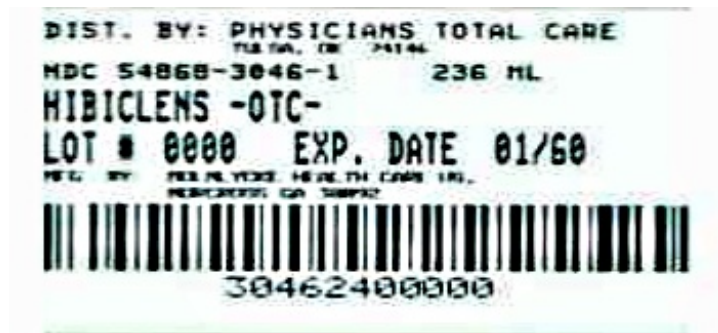
fragrance, isopropyl alcohol 4% w/v, purified water, Red 40, and other ingredients in a nonalkaline base.

Questions?

1-800-843-8497

PRINCIPAL DISPLAY PANEL - 236 mL Bottle Label

NDC 54868-3046-1



HIBICLENS®
*(Chlorhexidine Gluconate
solution 4.0% w/v)*

Antiseptic/Antimicrobial Skin Cleanser

HIBICLENS® prevents skin infections thereby reducing the risk of cross-infection. HIBICLENS® has antiseptic activity and a persistent antimicrobial effect with rapid bactericidal activity against a wide range of microorganisms.

MÖLNLYCKE®
HEALTH CARE

8 Fl. oz. (236 mL)

Distributed by Mölnlycke Health Care US, LLC
Norcross, GA 30092

Additional barcode labeling by:
Physicians Total Care, Inc.
Tulsa, Oklahoma 74146

HIBICLENS

chlorhexidine gluconate solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54868-3046(NDC:0234-0575)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	213 g in 1000 mL

Inactive Ingredients

Ingredient Name	Strength
Isopropyl alcohol (UNII: ND2M416302)	
FD&C Red NO. 40 (UNII: WZB9127XOA)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54868-3046-0	1 in 1 CARTON		
1		118 mL in 1 BOTTLE		
2	NDC:54868-3046-1	1 in 1 CARTON		
2		236 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA017768	11/17/2004	

Labeler - Physicians Total Care, Inc. (194123980)

Establishment

Name	Address	ID/FEI	Business Operations
Physicians Total Care, Inc.		194123980	relabel(54868-3046)

