

**FOAMING CHLORHEXIDINE GLUCONATE- chlorhexidine gluconate liquid**  
**Protect U Guard, LLC**

*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.*

-----

**Active Ingredient**

Chlorhexidine gluconate 4% w/v

**Purpose**

Antiseptic

**Uses**

Antimicrobial skin cleanser helps reduce bacteria  
for skin wound and skin cleansing  
surgical hand scrub  
healthcare personnel handwash

**Warnings**

For external use only.

**Do Not Use**

if you are allergic to chlorhexidine gluconate or any other ingredient(s) in this preparation  
as a patient preoperative skin preparation of the head or face  
in contact with the meninges or in the genital area  
on wounds involving more than the superficial layers of skin  
as a general skin cleanser

**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

do not inhale or ingest

### **Keep out of reach of children**

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

### **Stop use and ask a doctor if**

irritation, sensitization, or allergic reaction occurs and lasts 72 hours. These may be signs of a serious condition.

### **Directions**

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

skin wound and skin cleansing. Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of the product 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 5mL of the product with brush. Rinse thoroughly under running water. Repeat. Dry thoroughly.

healthcare personnel handwash. Wet hands with water. Dispense 5 mL of the product into cupped hands. Wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly.

### **Other Information**

May discolor some fabrics. Do not use with bleach.

Store between 20-25° C ( 68-77° F). Avoid excessive heat.

### **Inactive ingredients:**

Water, lauramine oxide, isopropyl alcohol, gluconolactone.

### **Questions or comments?**

1-813-815-0530 or [www.protectuguard.com](http://www.protectuguard.com)

Made In USA

Re-Order: P17051 Carton: P27051  
www.protectuguard.com



*Foaming*  
**CHLORHEXIDINE SOAP 4%**

Fragrance Free

Chlorhexidine Gluconate - 4% w/v  
Dye-Free



Manufactured by Protect U Guard, LLC Tampa, FL

18 fl oz (530 ml)

<b>Drug Facts</b>		<b>Drug Facts (Continued)</b>	
<b>Active Ingredient</b> Chlorhexidine gluconate 4% w/v	<b>Purpose</b> Antiseptic	<b>Keep out of reach of children.</b> If swallowed get medical help or contact a Poison Control Center right away.	
<b>Uses</b>		<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>Antimicrobial skin cleanser helps reduce bacteria</li> <li>for skin wound and skin cleansing</li> <li>surgical hand scrub</li> <li>healthcare personnel handwash</li> </ul>		Irritation, sensitization, or allergic reaction occurs and lasts 72 hours. These may be signs of a serious condition	
<b>Warnings</b>		<b>Directions</b>	
<b>For external use only.</b>		<ul style="list-style-type: none"> <li>use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.</li> </ul>	
<b>Do Not Use</b>		<ul style="list-style-type: none"> <li>skin wound and general skin cleansing. Thoroughly rinse the area to be cleansed with water. Apply the minimum amount of the product necessary to cover the skin or wound area and wash gently. Rinse thoroughly.</li> <li>surgical hand scrub. Wet hands and forearms with water. Scrub for 3 minutes with 5mL of the product with brush. Rinse thoroughly under running water. Repeat.</li> <li>healthcare personnel handwash. Wet hands with water. Dispense 5 mL of the product into cupped hands. Wash in a vigorous manner for 15 seconds. Rinse and dry thoroughly.</li> </ul>	
<b>When using this product</b>		<b>Other information</b>	
<ul style="list-style-type: none"> <li>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.</li> <li>if contact occurs in any of these areas, rinse with cold water right away</li> <li>Do not inhale or ingest.</li> </ul>		<ul style="list-style-type: none"> <li>May discolor some fabrics. Do not use with bleach</li> <li>Store between 20-25°C (68-77°F). Avoid excessive heat.</li> </ul>	
		<b>Inactive Ingredients:</b> Water, lauramine oxide, isopropyl alcohol, gluconolactone.	
		<b>Questions or comments?</b> 1-813-815-0530 or www.protectuguard.com	

Laundering information: Chlorhexidine skin cleansers will cause stains when used with chlorine releasing products, such as chlorine bleach. Rinse completely and use only non-chlorine detergents.

# FOAMING CHLORHEXIDINE GLUCONATE

chlorhexidine gluconate liquid

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71788-016
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLORHEXIDINE GLUCONATE</b> (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII:R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	4 g in 100 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71788-016-80	24 in 1 CARTON	04/13/2021	
1	NDC:71788-016-70	100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:71788-016-20	4 in 1 CARTON	04/13/2021	
2	NDC:71788-016-10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:71788-016-60	12 in 1 CARTON	04/13/2021	
3	NDC:71788-016-50	530 mL in 1 BOTTLE, PUMP; 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	part349	04/13/2021	

**Labeler** - Protect U Guard, LLC (080070945)

## Establishment

Name	Address	ID/FEI	Business Operations
Protect U Guard, LLC		080070945	manufacture(71788-016) , pack(71788-016) , repack(71788-016)

Revised: 4/2021

Protect U Guard, LLC