

**SCRUB, SCRUB-STAT- chlorhexidine gluconate solution**  
**Bajaj Medical, LLC**

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**Drug Facts**

Chlorhexidine gluconate, 4%

**Purposes**

Surgical hand scrub

Healthcare personnel handwash

Skin wound and general skin cleanser

**Uses**

- **surgical hand scrub:** significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care
- **healthcare personnel handwash:** handwash to help reduce bacteria that potentially can cause disease
- **skin wound and general cleanser:** helps reduce bacteria on the skin

**Warnings**

For external use only

**Allergy Alert**

this product may cause a severe allergic reaction.

Symptoms may include:

- wheezing/difficulty breathing
- shock
- facial swelling
- hives
- rash

If an allergic reaction occurs, stop use and seek medical help right away.

**Do not use**

- if you are allergic to chlorhexidine gluconate or any other ingredients in this preparation
- as a patient preoperative skin preparation (especially on the head or face)
- in contact with meninges
- in the genital area

**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 ear drums
- if contact occurs, rinse with cold water right away
- wounds which involve more than the superficial layers of the skin should not be routinely treated
- repeated general skin cleansing of large body areas should not be done except when underlying condition makes it necessary to reduce the bacterial population of the skin

**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 immediately

**Directions**

- use with care in premature infants or infants under 2 months of age. These product may cause irritation or chemical burns.
- use full strength
- do not dilute

**Surgical hand scrub:**

- remove jewelry
- wet hands and forearms with water and apply 5 mL of the product
- wash/scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces
- rinse thoroughly with water
- wash for an additional 3 minutes with 5 mL of the product and rinse under running water
- dry thoroughly

**Healthcare personnel handwash**

- wet hands with water
- dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 30 seconds
- rinse and dry thoroughly

**Skin wound and general skin cleanser**

- thoroughly rinse the area to be cleansed with water
- apply the minimum amount of product necessary to cover the skin or wound area and wash gently. Rinse thoroughly with water.
- rinse again thoroughly

**Other information**

- store between 20-25 °C (68-77 °F)
- avoid excessive heat above 40 °C(104 °F) for additional information, see Safety Data Sheet (SDS)
- if swallowed get medical help or contact a Poison Control Center immediately

**Inactive ingredients**

cocamide DEA, cocamine oxide, fragrance, gluconic acid\*, gluconolactone\*, hydroxyethylcellulose, isopropyl alcohol 4%, PEG-75 lanolin, PEG-150 distearate, propylene glycol, quaternium-60, water

\*contains one or more of these ingredients

**Questions or comments?**

Call +1.773.657.4777, 24 hours a day, 7 days a week

# Representative label and principal display panel



<b>Drug Facts</b> (continued)	
thoroughly with water	
<ul style="list-style-type: none"> <li>rinse again thoroughly</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>store at 20-25°C (68-77°F)</li> <li>avoid excessive heat above 40°C (104°F)</li> <li>for additional information, see Safety Data Sheet (SDS)</li> <li>if swallowed get medical help or contact a Poison Control Center immediately</li> </ul>	
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<b>Drug Facts</b>	
<b>Active ingredient</b>	<b>Purposes</b>
Chlorhexidine gluconate solution, 4%.....	Surgical hand scrub Healthcare personnel handwash Skin wound and general skin cleanser
<b>Uses</b>	
<ul style="list-style-type: none"> <li><b>surgical hand scrub:</b> significantly reduces the number of microorganisms on the hands and forearms prior to surgery or patient care</li> <li><b>healthcare personnel handwash:</b> handwash to help reduce bacteria that potentially can cause disease</li> <li><b>skin wound and general skin cleanser:</b> helps reduce bacteria on the skin</li> </ul>	
<b>Warnings</b>	
For external use only	
▲ Lift Here	

<b>Drug Facts</b> (continued)
<b>Allergy Alert</b>
<p>this product may cause a severe allergic reaction. Symptoms may include:</p> <ul style="list-style-type: none"> <li>wheezing/difficulty breathing</li> <li>shock</li> <li>facial swelling</li> <li>hives</li> <li>rash</li> </ul> <p>If an allergic reaction occurs, stop use and seek medical help right away.</p>
<b>Do not use</b>
<ul style="list-style-type: none"> <li>if you are allergic to chlorhexidine gluconate or any other ingredients in this preparation</li> <li>as a patient preoperative skin preparation (especially on the head or face)</li> <li>in contact with meningis</li> <li>in the genital area</li> </ul>
<b>When using this product</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, rinse with cold water right away</li> <li>wounds which involve more than the superficial layers of the skin should not be routinely treated</li> <li>repeated general skin cleansing of large body areas should not be done except when underlying condition makes it necessary to reduce the bacterial population of the skin</li> </ul>
<b>Stop use and ask a doctor</b> if irritation, sensitization or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition
<b>Keep out of reach of children</b>
if swallowed, get medical help or contact a Poison Control Center immediately
<b>Directions</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> <li>use full strength</li> <li>do not dilute</li> </ul>
<b>Surgical hand scrub:</b>
<ul style="list-style-type: none"> <li>remove jewelry</li> <li>wet hands and forearms with water and apply 5mL of the product</li> <li>wash/scrub hands and forearms for 3 minutes paying particular attention to the nails, cuticles, and interdigital spaces</li> <li>rinse thoroughly with water</li> <li>wash for an additional 3 minutes with 5 mL of the product and rinse under running water</li> <li>dry thoroughly</li> </ul>
<b>Healthcare personnel handwash:</b>
<ul style="list-style-type: none"> <li>wet hands with water</li> <li>dispense about 5 mL of product into cupped hands and wash in a vigorous manner for 30 seconds</li> <li>rinse and dry thoroughly</li> </ul>
<b>Skin wound and general skin cleanser:</b>
<ul style="list-style-type: none"> <li>thoroughly rinse the area to be cleansed with water</li> <li>apply the minimum amount of product necessary to cover the skin or wound area and wash gently. Rinse</li> </ul>

## SCRUB, SCRUB-STAT chlorhexidine gluconate solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61037-421
<b>Route of Administration</b>	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
COCAMINE OXIDE (UNII: QWA2IZI6FI)	

<b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)
<b>PEG-75 LANOLIN</b> (UNII: 09179OX7TB)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>COCO DIETHANOLAMIDE</b> (UNII: 92005F972D)
<b>GLUCONIC ACID</b> (UNII: R4R8J0Q44B)
<b>HYDROXYETHYL CELLULOSE (3000 CPS AT 1%)</b> (UNII: 7Q6P4JN1QT)
<b>PEG-150 DISTEARATE</b> (UNII: 6F36Q0I0AC)
<b>QUATERNIUM-33</b> (UNII: XPS4174QZJ)
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)
<b>WATER</b> (UNII: 059QF0KO0R)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61037-421-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
2	NDC:61037-421-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
3	NDC:61037-421-03	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
4	NDC:61037-421-04	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
5	NDC:61037-421-05	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
6	NDC:61037-421-06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
7	NDC:61037-421-07	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
8	NDC:61037-421-08	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
9	NDC:61037-421-09	237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
10	NDC:61037-421-10	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
11	NDC:61037-421-11	540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
12	NDC:61037-421-12	750 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
13	NDC:61037-421-13	750 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
14	NDC:61037-421-14	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
15	NDC:61037-421-15	800 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
16	NDC:61037-421-16	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
17	NDC:61037-421-17	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	
18	NDC:61037-421-18	1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
19	NDC:61037-421-19	1000 mL in 1 POUCH; Type 0: Not a Combination Product	07/22/1986	
20	NDC:61037-421-20	1250 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
21	NDC:61037-421-	1250 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination	07/22/1986	

21	Product	07/22/1986	
22	NDC:61037-421-22 30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
23	NDC:61037-421-23 59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/22/1986	
24	NDC:61037-421-24 118 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/22/1986	
25	NDC:61037-421-25 237 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	07/22/1986	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA019258	07/22/1986	

**Labeler** - Bajaj Medical, LLC (078774921)

**Registrant** - Bajaj Medical, LLC (078774921)

### Establishment

Name	Address	ID/FEI	Business Operations
Bajaj Medical, LLC		078774921	analysis(61037-421) , manufacture(61037-421) , relabel(61037-421) , repack(61037-421)

Revised: 7/2016

Bajaj Medical, LLC