# CHLORHEXIDINE GLUCONATE SOLUTION 0.75% ANTISEPTIC- chlorhexidine gluconate solution 0.75% antiseptic solution Bajaj Medical, LLC

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#### **Drug Facts**

#### Active ingredient

Chlorhexidine gluconate solution, 0.75%

#### **Purpose**

**Antiseptic** 

#### Use

• **healthcare personnel handwash:** helps reduce bacteria that potentially can cause disease

#### 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 ingredient in this product

#### When using this product

- keep out of eyes, ears, and mouth. May cause serious and permanent eye injury if permitted to enter and remain in the eye or may cause deafness when instilled in the middle ear through perforated eardrums.
- if solution should contact these areas, rinse out promptly and thoroughly with water
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

#### 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 and infants under 2 months of age. These products may cause irritation or chemical burns.

#### **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

#### Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

#### Inactive ingredients

citric acid, cocamide DEA, FD&C yellow #5, FD&C red #4, fragrance, hydroxyethylcellulose, isopropyl alcohol, lauramine oxide, purified water, ricinoleamidopropyl trimethyl ammonium chloride

#### Questions or comments?

call **1-800-581-2528**, 24 hours a day, 7 days a week

#### Package/Label Principal Display Panel

**Chlorhexidine Gluconate Solution** 

0.75%

#### ANTISEPTIC

FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

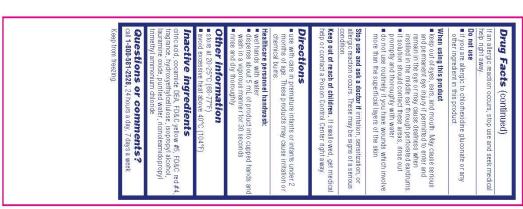
4 fl oz (118 mL)

NDC 61037-414-01

MADE IN THE USA







#### **ANTISEPTIC**

#### FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

8 fl oz (236 mL)

NDC 61037-414-02

MADE IN THE USA

**FDA APPROVED** 



#### **Chlorhexidine Gluconate Solution**

0.75%

**ANTISEPTIC** 

FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

16 fl oz (473 mL)

NDC 61037-414-05

MADE IN THE USA

#### **FDA APPROVED**



#### **Chlorhexidine Gluconate Solution**

0.75%

#### **ANTISEPTIC**

#### FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

32 fl oz (946 mL)

NDC 61037-414-06

**MADE IN THE USA** 



#### Chlorhexidine Gluconate Solution

0.75%

**ANTISEPTIC** 

FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

128 fl oz (3785 mL)

NDC 61037-414-07

MADE IN THE USA



#### **Chlorhexidine Gluconate Solution**

0.75%

#### **ANTISEPTIC**

#### FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

8 fl oz (236 mL)

NDC 61037-414-03

#### MADE IN THE USA

#### **FDA APPROVED**









#### **Chlorhexidine Gluconate Solution**

#### **ANTISEPTIC**

#### FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

8 fl oz (236 mL)

NDC 61037-414-04

#### **MADE IN THE USA**

#### **FDA APPROVED**









#### Chlorhexidine Gluconate Solution

0.75%

**ANTISEPTIC** 

FOR EXTERNAL USE ONLY

Bajaj Medical

Chicago IL 60609

40.6 fl oz (1.2 L)

NDC 61037-414-08

MADE IN THE USA



## **Chlorhexidine Gluconate** Solution

### ANTISEPTIC

FOR EXTERNAL USE ONLY

40.6 fl oz (1.2 L)



## **Drug Facts**

**Active ingredient** 

Chlorhexidine gluconate solution, 0.75%...

**Purpose** 

Antiseptic

Lift Here for Drug Facts

#### Drug Facts (continued)

#### Use

healthcare personnel handwash: helps reduce bacteria that potentially can cause disease

#### 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.

if you are allergic to chlorhexidine gluconate or any other ingredient in this product

#### When using this product

keep out of eyes, ears, and mouth. May cause serious and permanent eye injury

#### Drug Facts (continued)

if permitted to enter and remain in the eve or may cause deafness when instilled in the middle ear through perforated eardrums.

- if solution should contact these areas. rinse out promptly and thoroughly with
- do not use routinely if you have wounds which involve more than the superficial layers of the skin

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. Þ



Keep from freezing.

#### **CHLORHEXIDINE GLUCONATE SOLUTION 0.75% ANTISEPTIC**

chlorhexidine gluconate solution 0.75% antiseptic solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61037-414
Route of Administration	TOPICAL		

l	Active Ingredient/Active Moiety				
l	Ingredient Name	<b>Basis of Strength</b>	Strength		
	CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E) (CHLORHEXIDINE - UNII: R4KO0DY52L)	CHLORHEXIDINE GLUCONATE	0.75 mg in 100 mL		

Inactive Ingredients		
Ingredient Name	Strength	
COCO DIETHANOLAMIDE (UNII: 92005F972D)		
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)		
ISOPROPYL ALCOHOL (UNII: ND2M416302)		
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)		
RICINOLEAMIDOPROPYLTRIMONIUM CHLORIDE (UNII: 930U7D1C3U)		
WATER (UNII: 059QF0KO0R)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1 LX)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61037- 414-01	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2014		
2	NDC:61037- 414-02	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2014		
3	NDC:61037- 414-05	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2014		
4	NDC:61037- 414-06	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2014		
5	NDC:61037- 414-07	3785 mL in 1 JUG; Type 0: Not a Combination Product	09/30/2014		
6	NDC:61037- 414-03	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/12/2017		
7	NDC:61037- 414-04	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	10/12/2017		
8	NDC:61037- 414-08	1200 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	10/12/2017		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020111	09/30/2014	

## Labeler - Bajaj Medical, LLC (078774921)

## Registrant - Bajaj Medical, LLC (078774921)

Establishment			
Name	Address	ID/FEI	Business Operations
Bajaj Medical, LLC		078774921	label(61037-414) , analysis(61037-414) , manufacture(61037-414) , pack(61037-414)

Revised: 12/2022 Bajaj Medical, LLC