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

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

8 fl oz (236 mL)

NDC 61037-413-02

MADE IN THE USA

FDA APPROVED

Keep from freezing.

⚠ WARNING: This product can expose you to cocamide DEA, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov

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		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**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: 93OU7D1C3U)	
WATER (UNII: 059QF0KO0R)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

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) , repack(61037-414) , relabel(61037-414)