

**PUROMA ANTIBACTERIAL FOAMING HAND WASH FRAGRANCE FREE-  
benzalkonium chloride liquid  
ZENITH MICRO CONTROL**

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***Drug Facts***

***Active ingredient***

Benzalkonium chloride 0.13%

***Purpose***

Antibacterial

***Uses***

Helps eliminate bacteria on hands.

***Warnings***

- **For external use only.**
- **When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- **Stop use and ask a doctor if** irritation or rash appears and lasts.

**Keep out of reach of children**

except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away.

***Directions***

Wet hands and wrists with clean running water.  
Apply appropriate amount of product.  
Lather and scrub hands, fingers, fingernails, cuticles and wrists thoroughly.  
Rinse thoroughly with running water.  
Dry hands completely.

***Inactive ingredients***

Water, Glycerin, Methylchloroisoithiazolinone, Methylisoithiazolinone, Cetrimonium Chloride, Lauramidopropylamine Oxide, Coco Monoethanolamide, Propylene Glycol, Citric Acid Monohydrate, Phenoxyethanol, Edetate Sodium, Decyl Glucoside, Coco Glucoside, Glyceril Oleate, Cocamidopropyl Betaine, Lauramine Oxide, Behentrimonium

Chloride, PEG-7 Glyceryl Cocoate, Cocamidopropyl Hydroxysultaine, Polysorbate 20, Sodium Chloride, FD&C Green No.3.

**Other information**

Store below 104°F (40°C)

**Product label**

**Drug Facts** (continued)

**Directions**

- Wet hands and wrists with clean running water.
- Apply appropriate amount of product.
- Lather and scrub hands, fingers, fingernails, cuticles and wrists thoroughly.
- Rinse thoroughly with running water.
- Dry hands completely.

**Other information**

- Store below 104°F (40°C).

**Inactive ingredients:**  
 Water (Aqua),Behentrimonium Chloride, Cetrimonium Chloride,Coco Monoethanolamide, Citric Acid Monohydrate,Coco Glucoside, Cocamidopropyl Betaine, Cocamidopropyl Hydroxysultaine,Decyl Glucoside,Edetate Sodium ,Glyceril Oleate,Glycerin, Lauramine Oxide, Lauramidopropylamine Oxide ,Methylchlorisothiazolinone, Methylisothiazolinone, Propylene Glycol,PEG-7 Glyceryl Cocoate, Phenoxyethanol,Sodium Chloride,Polysorbate 20,FD&C Green No.3

**PUROMA**

**ANTIBACTERIAL FOAMING HAND WASH**

with added Moisturizers

Kills **99.9 %** of illness causing germs

Fragrance Free

6.76 FL OZ (200 ml)

**Drug Facts**

Active ingredient	Purpose
Benzalkonium Chloride	
0.13%-----	Antibacterial.

**Uses**

- Helps eliminate bacteria on hands.

**Warnings**

**For external use only.**

**When using this product** do not use in or near the eyes.In case of contact,rinse eyes thoroughly with water.

**Stop use and ask a doctor** if irritation or rash appears and lasts.

**Keep out of reach of children** except under adult supervision. If swallowed, get medical help or contact a Poison Control Center right away

Made In India

Distributed by:  
 Infinity BioSolutions Inc.  
 1025 Alameda De Las Pulgas, Suite 423,Beimont, CA 94002. Tel. +1-877-778-7662.

Batch No :  
 Expiry Date :

<b>PUROMA ANTIBACTERIAL FOAMING HAND WASH FRAGRANCE FREE</b>			
benzalkonium chloride liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:80948-005
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>	
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	130 mg in 100 mL	

## Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>METHYLCHLOROISOTHIAZOLINONE</b> (UNII: DEL7T5QRPN)	
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)	
<b>CETRIMONIUM CHLORIDE</b> (UNII: UC9PE95IBP)	
<b>LAURAMIDOPROPYLAMINE OXIDE</b> (UNII: I6KX160QTV)	
<b>COCO MONOETHANOLAMIDE</b> (UNII: C80684146D)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>COCO GLUCOSIDE</b> (UNII: ICS790225B)	
<b>GLYCERYL OLEATE</b> (UNII: 4PC054V79P)	
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)	
<b>LAURAMINE OXIDE</b> (UNII: 4F6FC4MI8W)	
<b>BEHENTRIMONIUM CHLORIDE</b> (UNII: X7GNG3S47T)	
<b>PEG-7 GLYCERYL COCOATE</b> (UNII: VNX7251543)	
<b>COCAMIDOPROPYL HYDROXYSULTAINE</b> (UNII: 62V75NI93W)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80948-005-01	4 in 1 PACKAGE	03/10/2021	
1		70 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:80948-005-02	6 in 1 PACKAGE	03/10/2021	
2		70 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:80948-005-03	8 in 1 PACKAGE	03/10/2021	
3		70 mL in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:80948-005-04	12 in 1 PACKAGE	03/10/2021	
4		70 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:80948-005-05	24 in 1 PACKAGE	03/10/2021	
5		70 mL in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:80948-005-06	4 in 1 PACKAGE	03/10/2021	
6		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
	NDC:80948-			

<b>7</b>	NDC:80948-005-07	6 in 1 PACKAGE	03/10/2021	
<b>7</b>		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>8</b>	NDC:80948-005-08	8 in 1 PACKAGE	03/10/2021	
<b>8</b>		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>9</b>	NDC:80948-005-09	12 in 1 PACKAGE	03/10/2021	
<b>9</b>		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>10</b>	NDC:80948-005-10	24 in 1 PACKAGE	03/10/2021	
<b>10</b>		100 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>11</b>	NDC:80948-005-11	4 in 1 PACKAGE	03/10/2021	
<b>11</b>		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>12</b>	NDC:80948-005-12	6 in 1 PACKAGE	03/10/2021	
<b>12</b>		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>13</b>	NDC:80948-005-13	8 in 1 PACKAGE	03/10/2021	
<b>13</b>		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>14</b>	NDC:80948-005-14	12 in 1 PACKAGE	03/10/2021	
<b>14</b>		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>15</b>	NDC:80948-005-15	24 in 1 PACKAGE	03/10/2021	
<b>15</b>		150 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>16</b>	NDC:80948-005-21	4 in 1 PACKAGE	03/10/2021	
<b>16</b>		200 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
<b>17</b>	NDC:80948-005-22	6 in 1 PACKAGE	03/10/2021	
<b>17</b>		200 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
<b>18</b>	NDC:80948-005-23	8 in 1 PACKAGE	03/10/2021	
<b>18</b>		200 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
<b>19</b>	NDC:80948-005-24	12 in 1 PACKAGE	03/10/2021	
<b>19</b>		200 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
<b>20</b>	NDC:80948-005-25	24 in 1 PACKAGE	03/10/2021	
<b>20</b>		200 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
<b>21</b>	NDC:80948-005-26	4 in 1 PACKAGE	03/10/2021	
<b>21</b>		220 mL in 1 BOTTLE; Type 0: Not a Combination Product		

<b>22</b>	NDC:80948-005-27	6 in 1 PACKAGE	03/10/2021	
<b>22</b>		220 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>23</b>	NDC:80948-005-28	8 in 1 PACKAGE	03/10/2021	
<b>23</b>		220 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>24</b>	NDC:80948-005-29	12 in 1 PACKAGE	03/10/2021	
<b>24</b>		220 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>25</b>	NDC:80948-005-30	24 in 1 PACKAGE	03/10/2021	
<b>25</b>		220 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>26</b>	NDC:80948-005-31	2 in 1 PACKAGE	03/10/2021	
<b>26</b>		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>27</b>	NDC:80948-005-32	4 in 1 PACKAGE	03/10/2021	
<b>27</b>		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>28</b>	NDC:80948-005-33	6 in 1 PACKAGE	03/10/2021	
<b>28</b>		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>29</b>	NDC:80948-005-34	8 in 1 PACKAGE	03/10/2021	
<b>29</b>		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>30</b>	NDC:80948-005-35	12 in 1 PACKAGE	03/10/2021	
<b>30</b>		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>31</b>	NDC:80948-005-36	24 in 1 PACKAGE	03/10/2021	
<b>31</b>		250 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>32</b>	NDC:80948-005-37	2 in 1 PACKAGE	03/10/2021	
<b>32</b>		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>33</b>	NDC:80948-005-38	4 in 1 PACKAGE	03/10/2021	
<b>33</b>		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>34</b>	NDC:80948-005-39	6 in 1 PACKAGE	03/10/2021	
<b>34</b>		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>35</b>	NDC:80948-005-40	8 in 1 PACKAGE	03/10/2021	
<b>35</b>		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
<b>36</b>	NDC:80948-005-41	12 in 1 PACKAGE	03/10/2021	
<b>36</b>		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		

37	NDC:80948-005-42	24 in 1 PACKAGE	03/10/2021	
37		300 mL in 1 BOTTLE; Type 0: Not a Combination Product		
38	NDC:80948-005-43	2 in 1 PACKAGE	03/10/2021	
38		350 mL in 1 BOTTLE; Type 0: Not a Combination Product		
39	NDC:80948-005-44	4 in 1 PACKAGE	03/10/2021	
39		350 mL in 1 BOTTLE; Type 0: Not a Combination Product		
40	NDC:80948-005-45	6 in 1 PACKAGE	03/10/2021	
40		350 mL in 1 BOTTLE; Type 0: Not a Combination Product		
41	NDC:80948-005-46	8 in 1 PACKAGE	03/10/2021	
41		350 mL in 1 BOTTLE; Type 0: Not a Combination Product		
42	NDC:80948-005-47	12 in 1 PACKAGE	03/10/2021	
42		350 mL in 1 BOTTLE; Type 0: Not a Combination Product		
43	NDC:80948-005-48	24 in 1 PACKAGE	03/10/2021	
43		350 mL in 1 BOTTLE; Type 0: Not a Combination Product		
44	NDC:80948-005-49	5000 mL in 1 CAN; Type 0: Not a Combination Product	03/10/2021	
45	NDC:80948-005-50	50000 mL in 1 CAN; Type 0: Not a Combination Product	03/10/2021	
46	NDC:80948-005-51	200000 mL in 1 DRUM; Type 0: Not a Combination Product	03/10/2021	
47	NDC:80948-005-52	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/21/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M003	03/10/2021	

**Labeler** - ZENITH MICRO CONTROL (915625571)

## Establishment

Name	Address	ID/FEI	Business Operations
ZENITH MICRO CONTROL		915625571	manufacture(80948-005)