**PLUS BRASEPT- benzalkonium chloride soap**
**NEWDROP NORTH AMERICA 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.*

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**PLUS BRASEPT 6265 Drug Facts and Label**

**Drug Facts Box OTC-Active Ingredient Section**

Benzalkonium Chloride 2.5%

**Drug Facts Box OTC-Purpose Section**

Antiseptic

**Drug Facts Box OTC-Indications & Usage Section**

for hand-washing to decrease bacteria on the skin

**Drug Facts Box OTC-Warnings Section**

For external use only

**Drug Facts Box OTC-When Using Section**

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

**Drug Facts Box OTC-Stop Use Section**

irritation and redness develop

**Drug Facts Box OTC-Keep Out of Reach of Children Section**

if swallowed, get medical help or contact a Poison Control Center right away

**Drug Facts Box OTC-Dosage & Administration Section**

- wet hands and forearms
- apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- scrub thoroughly for 1 minute and rinse

**Drug Facts Box OTC-Inactive Ingredient Section**

water, glycerin, isopropyl alcohol, disodium cocoamphodiproprionate, hydroxyethylcellulose, lauramine oxide,

PEG-75 lanolin, citric acid, FD and C red no.4

**PLUS BRASEPT 6265**


# PLUS BRASEPT

benzalkonium chloride soap

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:83318-265 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y) | BENZALKONIUM CHLORIDE | 25 mg in 1 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%)** (UNII: L605B5892V) | |
| **DISODIUM COCOAMPHODIPROPIONATE** (UNII: 6K8PRP397M) | |
| **LAURAMINE OXIDE** (UNII: 4F6FC4MI8W) | |
| **PEG-75 LANOLIN** (UNII: 09179OX7TB) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **FD&C RED NO. 4** (UNII: X3W0AM1JLX) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:83318-265-41 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/24/2023 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part333E | 03/23/2023 | |

## Labeler - NEWDROP NORTH AMERICA LLC (094392481)

## Registrant - ABC Compounding Co., Inc. (003284353)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| ABC Compounding Co., Inc. | | 003284353 | manufacture(83318-265) |

Revised: 3/2023 NEWDROP NORTH AMERICA LLC