

DANS ANTI-BACTERIAL BAR DETOX- benzalkonium chloride soap
HADA International S.A

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.

Dans Anti-bacterial Bar Soap Detox

Drug Facts

Active ingredient

Benzalkonium Chloride 0.1%

Purpose

Antibacterial

Use for washing to decrease bacteria on the skin

Warnings

For external use only

When using this product do not use in or near the eyes, in case of eye contact, flush with water

Stop use and ask a doctor if irritation or redness develop

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

Directions

- Wet bar with water
- Lather vigorously and wash skin
- Rinse and dry thoroughly

Inactive ingredients Sodium Palmate, Sodium Palm Kernelate, Water, Glycerin, Sodium Chloride, Fragrance, Etidronic Acid, Titanium Dioxide, Tetrasodium EDTA, Hydrolyzed Collagen, Avena Sativa (Oat) Bran, Mentha Piperita Leaf Extract, Chamomilla Recutita Flower Extract, Camellia Sinensis Leaf Extract, Yellow #10 (CI 47005), Green No. 3 (CI 42053).

Manufactured by:

HADA INTERNATIONAL, S.A.

Zona Franca La Cayena Km 8 LT7MZ8

Barranquilla, Columbia

Made in Columbia

Calls USA: +1 (787)7856822

Hada Dans®

ANTIBACTERIAL BAR SOAP

DETOX APPLE & GREEN TEA

With Collagen

NET WT 4.4 OZ (125g)

Drug Facts / Información del producto (Continued / Continuación)

Inactive ingredients: Sodium Palmate, Sodium Palm Kernelate, Water, Glycerin, Sodium Chloride, Fragrance, Ethionic Acid, Titanium Dioxide, Tetrasodium EDTA, Hydrolyzed Collagen, Avena Sativa (Oat) Kernel Extract, Mentha Piperita Leaf Extract, Chamomilla Recutita Flower Extract, Aloe Barbadosis Leaf Extract, Camellia Sinensis Leaf Extract, Amyl Cinnamal, Yellow No. 10 (CI 47005), Green No. 3 (CI 42053).

Ingredientes inactivos: Palmato de Sodio, Karmelato de Palma de sodio, Agua, Glicerina, Cloruro de Sodio, Fragancia, Ácido Etilénico, Dióxido de Titanio, EDTA Tetrasódico, Colágeno Hidrolizado, Extracto de Grano de Avena, Extracto de Hoja de Menta, Extracto de hoja de Aloe Vera, Extracto de hoja de Té, Amyl Cinnamal, Amarillo No. 10 (CI 47005), Verde No. 3 (CI 42053).

Drug Facts / Información del producto

Active ingredient / Ingrediente activo Benzalkonium Chloride 0.1% / Cloruro de Benzalkonio 0.1% **Purpose / Propósito** Antibacterial

Use / Uso For washing to decrease bacteria on the skin / Para lavar y disminuir las bacterias de la piel

Warnings / Advertencias For external use only / Solo para uso externo
When using this product do not use in or near the eyes. In case of eye contact, flush with water.
Al usar este producto evitar el contacto con los ojos. En caso de contacto con los ojos enjuagar con agua.
Stop use and ask a doctor if irritation or redness develop.
Deje de usar y pregúntele a un médico si se desarrolla irritación o enrojecimiento.

Directions / Direcciones
 Wet bar with water / Humedecer con agua. Lather vigorously and wash skin / Frota vigorosamente y enjuagar la piel.
 Rinse and dry thoroughly / Enjuagar y secar completamente.

DANS ANTI-BACTERIAL BAR DETOX

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42377-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-AMYL CINNAMALDEHYDE (UNII: WC51CA3418)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
HYDROLYSED BOVINE COLLAGEN (ENZYMATIC; 3500 MW) (UNII: 5WE8P977RQ)	
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	
GLYCERIN (UNII: PDC6A3C0OX)	
OAT BRAN (UNII: KQX236OK4U)	
WATER (UNII: 059QF0KO0R)	
SODIUM PALMATE (UNII: S0A6004K3Z)	
SODIUM PALM KERNELATE (UNII: 6H91L1NXTW)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MENTHA PIPERITA LEAF (UNII: A389O33LX6)	
ETIDRONIC ACID (UNII: M2F465ROXU)	
EDETATE SODIUM (UNII: MP1J8420LU)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
CHAMOMILE (UNII: FGL3685T2X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42377-012-04	125 g in 1 BOX; Type 0: Not a Combination Product	03/06/2020	
2	NDC:42377-012-14	3 in 1 BOX	03/06/2020	
2		125 g in 1 PACKAGE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/06/2020	

Labeler - HADA International S.A (882405152)

Establishment

Name	Address	ID/FEI	Business Operations
HADA International S.A.		882405152	manufacture(42377-012)

Revised: 4/2020

HADA International S.A