

MEDICALLY MINDED- benzalkonium chloride cloth
BELSKIN S. DE, R.L. DE C.V

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.

ANTICEPTIC WET WIPES

DOSAGE AND ADMINISTRATION

APPLY TO HANDS

ALLOW TO DRY WITHOUT WIPING

WARNINGS AND PRECAUTIONS

WHEN USING THIS PRODUCT DO NOT GET INTO EYES. IF CONTACT OCCURS, RINSE THOROUGHLY WITH WATER.

CHILDREN UNDER 2 YEARS ASK A DOCTOR BEFORE USE

WARNINGS

FOR EXTERNAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN. IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY.

STOP USE AND ASK A DOCTOR

STOP USE AND ASK A DOCTOR IF IRRITATION OR RASH DEVELOPS AND CONTINUES FOR MORE THAN 72 HOURS.

PURPOSE

ANTIMICROBIAL AGENT

ACTIVE INGREDIENT

BENZALKONIUM CHLORIDE

ETHYL ALCOHOL

INACTIVE INGREDIENT

WATER

ALOE VERA (ALOE BARBADENSIS) LEAF JUICE

ANHYDROUS CITRIC ACID

DIMETHICONE

ETHYLENE DIAMINE TETRAACETIC ACID TETRASODIUM SALT (EDTA-4Na)
 HYDANTOINE
 POLYSORBATE 20
 TOCOPHERYL ACETATE (VITAMIN E)
 GLYCERIN
 FRAGRANCE
 METHYLCHLOROISOTHIAZOLINONE
 METHYLISOTHIAZOLINONE

INDICATIONS AND USAGE

APPLY TO HANDS

ALLOW TO DRY WITHOUT WIPING

PACKAGE LABEL

Drug Facts

Active ingredient	Purpose
Benzalkonium Chloride 0.25%	Antimicrobial Agent

Uses: decreases bacterial on skin.

Warnings:
 For external use only.
 Do not use if you are allergic to any of the ingredients.
 When using this product do not get into eyes. If contact occurs, rinse thoroughly with water.
 Stop use and ask a doctor if irritation or rash develops and continues for more than 72 hours.
 Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

Directions:
 adults and children 7 years and over: apply to hands. allow to dry without wiping.
 children under 7 years: ask a doctor before to use.

Inactive ingredients:
 Water, Aloe Vera (Aloe Barbadensis), Leaf Juice, Anhydrous Citric Acid, Dimethicone, Ethylene Diamine, Tetraacetic Acid, Tetrasodium Salt (EDTA-4Na), Ethyl Alcohol Denat, Hydrantoina, Polysorbate 20, Tocopheryl Acetate (Vitamin E), Glycerin, Fragrance, Methylchloro-isothiazolinone, Methylisothiazolinone.

Questions or Comments?
 Call +52 33 33718679, M&F or contact by email to: hc@grupobelsa.com

PRECAUCIONES: Mantener fuera del alcance de los niños. Evitar tragar o introducir en la boca. En caso de contacto con los ojos lavar inmediatamente con agua limpia. Producto no apto para la higiene del cuerpo del bebé. Evitar irritación o sensibilidad, suspender su uso.

INSTRUCCIONES DE USO: Limpiar y desinfectar las manos con la toallita húmeda. No enjuagar. Tirar en la basura después de usarla. Para asegurar frescura, funcionalidad y humedad de la toallita, realizar la apertura de enfrente del empaque.

INGREDIENTES ACTIVOS:
 Cloruro de Benzalconio 0.250%

GRUPO BELSA
 Manufactura y Distribución:
 Fabricada y distribuida por:
 BELSA S. DE C.V. S. DE C.V.
 Industria 48 Avenida 82187
 Cd. Zapopan, Jalisco, México
 C.F. 45130
 Zapopan, Jalisco, México
 Tel: +52 33 33718679
 y 33846988
ventas@grupobelsa.com
www.grupobelsa.com
www.grubelsa.com

Hecho en México
 Made in México

7 503024 381818

MEDICALLY MINDED

benzalkonium chloride cloth

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78 502-6000

Route of Administration	TOPICAL
--------------------------------	---------

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.25 g in 100 g
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0K00R)	93.885 g in 100 g
ALOE VERA LEAF (UNII: ZY81Z83H0X)	0.05 g in 100 g
GLYCERIN (UNII: PDC6A3C0OX)	0.5 g in 100 g
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	0.1 g in 100 g
DIMETHICONE (UNII: 92RU3N3Y1O)	0.005 g in 100 g
EDETATE SODIUM TETRAHYDRATE (UNII: L13NHD21X6)	0.008 g in 100 g
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	0.1 g in 100 g
HYDANTOIN (UNII: I6208298TA)	0.002 g in 100 g
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	0.015 g in 100 g
POLYSORBATE 20 (UNII: 7T1F30V5YH)	0.005 g in 100 g
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	0.08 g in 100 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78502-6000-6	40 g in 1 BAG; Type 0: Not a Combination Product	06/28/2020	
2	NDC:78502-6000-7	30 g in 1 BAG; Type 0: Not a Combination Product	06/28/2020	
3	NDC:78502-6000-8	20 g in 1 BAG; Type 0: Not a Combination Product	06/28/2020	
4	NDC:78502-6000-9	10 g in 1 BAG; Type 0: Not a Combination Product	06/28/2020	
5	NDC:78502-6000-1	1 g in 1 BAG; Type 0: Not a Combination Product	06/28/2020	
6	NDC:78502-6000-2	5 g in 1 BAG; Type 0: Not a Combination Product	06/28/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	06/28/2020	

Labeler - BELSKIN S. DE, R.L. DE C.V (816649743)

Registrant - BELSKIN S. DE, R.L. DE C.V (816649743)

Establishment

Name	Address	ID/FEI	Business Operations
BELSKIN S. DE, R.L. DE C.V		816649743	manufacture(78502-6000)

