

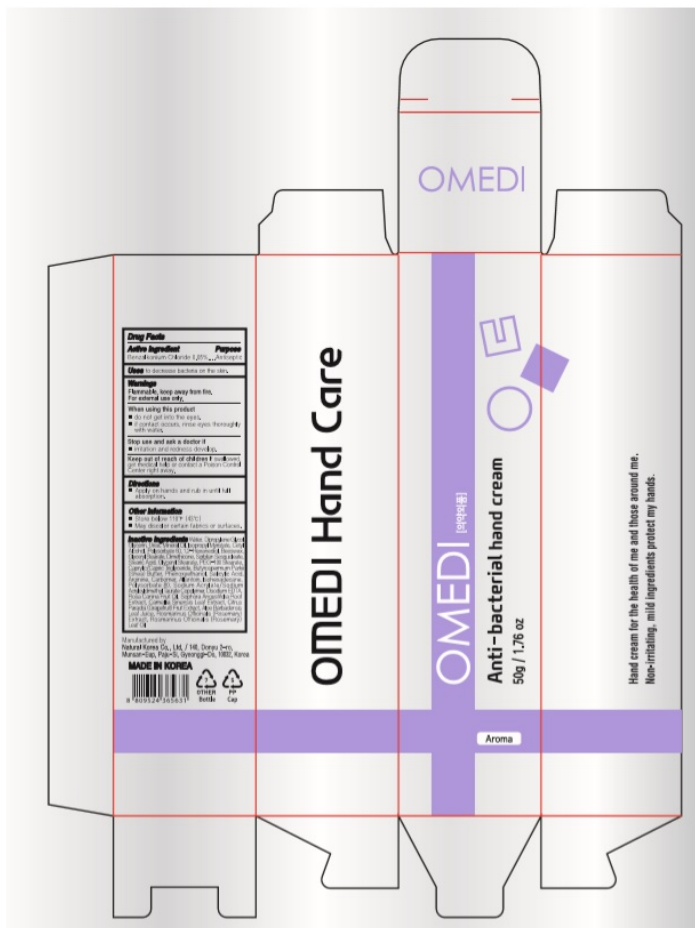
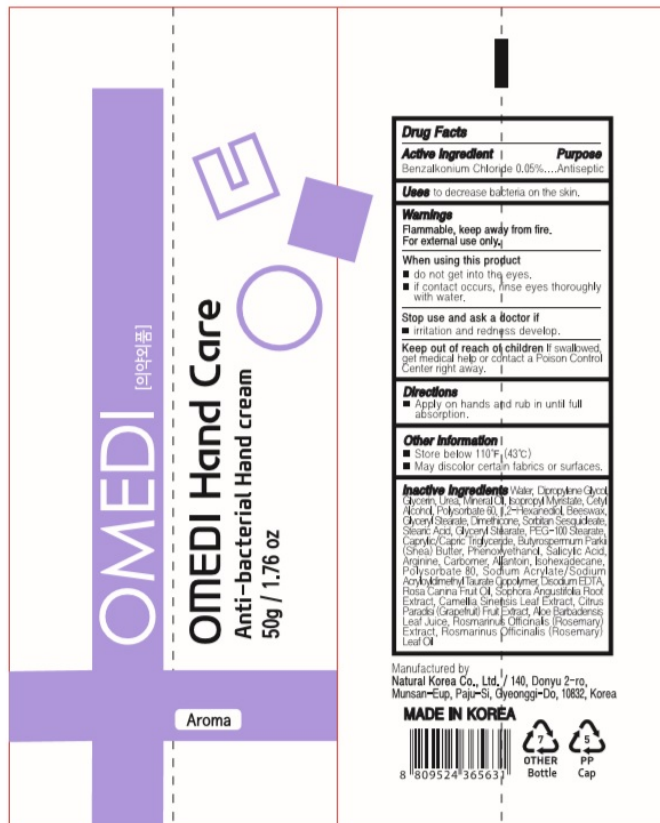
OMEDI ANTI-BACTERIAL HAND CREAM- benzalkonium chloride cream
Natural Korea Co., Ltd.

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.

OMEDI HAND CARE : OMEDI Anti-bacterial hand cream (Aroma)

74646-1050-1 : TUBE

74646-1050-2 : TUBE+BOX



OMEDI ANTI-BACTERIAL HAND CREAM

benzalkonium chloride cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74646-1050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.025 g in 50 g

Inactive Ingredients

Ingredient Name	Strength
STEARIC ACID (UNII: 4ELV7Z65AP)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (400000 MW) (UNII: 1DXE3F3OZX)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ALLANTOIN (UNII: 344S277G0Z)	
ISOHEXADECANE (UNII: 918X10UF1E)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
WATER (UNII: 059QF0K00R)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
UREA (UNII: 8W8T17847W)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
MINERAL OIL (UNII: T5L8T28FGP)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ROSEMARY OIL (UNII: 8LGU7VM393)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
SHEA BUTTER (UNII: K49155WL9Y)	
SALICYLIC ACID (UNII: O414PZ4LPZ)	
ARGININE (UNII: 94ZLA3W45F)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
ROSA CANINA FRUIT OIL (UNII: CR7307M3QZ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GRAPEFRUIT (UNII: O82C39RR8C)	
ROSEMARY (UNII: IJ67X351P9)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:74646-1050-2	1 in 1 BOX	05/29/2020	
1	NDC:74646-1050-1	50 g in 1 TUBE; 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	05/29/2020	

Labeler - Natural Korea Co., Ltd. (688729438)

Establishment

Name	Address	ID/FEI	Business Operations
Natural Korea Co., Ltd.		688729438	manufacture(74646-1050)

Revised: 5/2020

Natural Korea Co., Ltd.