

UNIWELL NATURAL ESSENCE- dimethicone emulsion
uniwell 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.

Drug Facts

DIMETHICONE 1.875%

Skin Protectant

Helps prevent and temporarily protects chafed, chapped or cracked skin.

Helps prevent and protect from the drying effects of wind and cold weather.

Apply as needed.

For external use only.

Do not use on deep or puncture wounds, animal bites, or serious burns.

Stop use and ask a doctor if condition worsen, symptoms last more than 7 days or clean up and occur again within a few days.

Keep out of reach of the children. If product is swallowed, get medical help or contact a poison control center right away.

Water, Butylene Glycol, Glycerin, 1,2-Hexanediol, Niacinamide, Dimethicone/Vinyl Dimethicone Crosspolymer, Squalane, Arginine, Carbomer, Propanediol, Polyacrylate-13, Hydroxyacetophenone, Polyisobutene, Citrus Aurantium Dulcis (Orange) Oil, Allantoin, Dipotassium Glycyrrhizate, Adenosine, Ethylhexylglycerin, Polysorbate 20, Phenoxyethanol, Theobroma Cacao (Cocoa) Extract, Sorbitan Isostearate, Disodium EDTA, Beta-Glucan, Dextrin, Ecklonia cava Extract, Glycine Soja (Soybean) Sprout Extract, Triticum Vulgare (Wheat) Sprout Extract, Brassica Oleracea Italica (Broccoli) Sprout Extract, Camellia Oleifera Leaf Extract, Magnolia Liliflora Flower Extract, Eugenia Caryophyllus (Clove) Bud Extract, Sophora Japonica Flower Extract, Lavandula Angustifolia (Lavender) Oil, Citrus Limon (Lemon) Peel Oil, Alcohol, Phenoxyethanol, Sodium Hyaluronate



UNIWELL NATURAL ESSENCE

dimethicone emulsion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71502-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.937 mg in 50 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
Butylene Glycol (UNII: 3XUS85K0RA)	
Glycerin (UNII: PDC6A3C0OX)	
1,2-Hexanediol (UNII: TR046Y3K1G)	
NIACINAMIDE (UNII: 25X51I8RD4)	
Squalane (UNII: GW89575KF9)	
Arginine (UNII: 94ZLA3W45F)	
Propanediol (UNII: 5965N8W85T)	
POLYACRYLAMIDE (1500 MW) (UNII: 5D6TC4BRWV)	
2-HYDROXYACETOPHENONE (UNII: DQ1N9R01IA)	
POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52)	
ORANGE OIL (UNII: AKN3KSD11B)	
Allantoin (UNII: 344S277G0Z)	
GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX)	
Adenosine (UNII: K72T3FS567)	
Ethylhexylglycerin (UNII: 147D247K3P)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
COCOA (UNII: D9108TZ9KG)	
SORBITAN ISOSTEARATE (UNII: 01S2G2C1E4)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
ECKLONIA CAVA (UNII: UXX2N5V39P)	
SOYBEAN (UNII: L7HT8FIZOD)	
WHEAT SPROUT (UNII: 3K32950CI0)	
BROCCOLI SPROUT (UNII: 128UH9LOAE)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
MAGNOLIA LILIFLORA FLOWER (UNII: SVM28292LH)	
CLOVE (UNII: K48IKT5321)	
STYPHNOLOBIUM JAPONICUM FLOWER (UNII: 644C3CSB6E)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
LEMON OIL (UNII: I9GRO824LL)	
ALCOHOL (UNII: 3K9958V90M)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71502-002-02	1 in 1 PACKAGE	06/12/2017	
1	NDC:71502-002-01	50 mL in 1 CONTAINER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/12/2017	

Labeler - uniwell LTD (694646565)

Registrant - uniwell LTD (694646565)

Establishment

Name	Address	ID/FEI	Business Operations
Cosmecca Korea Co., Ltd.		688830827	manufacture(71502-002)

Revised: 6/2017

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