

METABOLIC BRIGHTENING BB CUSHION- titanium dioxide, zinc oxide, alpha bisabolol powder rootsallo Qwell

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACTIVE INGREDIENTS

Titanium Dioxide 11.51%
Zinc Oxide 4.75%
.ALPHA.-BISABOLOL, (+/-)- 0.5%

PURPOSE

Sunscreen, Brightening

Uses

Helps to keep the bright skin tone with excellent coverage.

Warnings

For external use only.
In case of having side effects such as red rash, swollenness and/or itching while using this cosmetic consult a dermatologist immediately.
Keep out of reach of children.

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Directions

Using puff applicator, press down lightly onto pre-saturated cushion sponge to capture product and pat evenly over face.

Other Information

Do not store this product in an inappropriate place such as high or low temperatures or under direct sun light.

Questions

Inactive ingredients

Water, Isoamyl Laurate, Caprylic/Capric Triglyceride, Oenothera Biennis (Evening Primrose) Oil, Macadamia Integrifolia Seed Oil, Polyglyceryl-3 Polyricinoleate, Sorbitan Olivatate, Glycerin, Sodium Chloride, Scutellaria Baicalensis Root Extract, Hydrogenated Olive Oil, Propanediol, Glyceryl Caprylate, Lauroyl Lysine, Betaine, Chamaecyparis Obtusa Oil, Olea Europaea (Olive) Fruit Oil, Aluminum Hydroxide, Citric Acid, Magnesium Stearate, Iron Oxide Red, Arginine, Stearic Acid, p-Anisic Acid, Tocopherol, Iron Oxide Black, Olea Europaea (Olive) Oil Unsaponifiables, Mica, Sodium Hyaluronate, Magnesium Palmitate, Centella Asiatica Extract, Aloe Barbadensis Leaf Extract, Polygonum Cuspidatum Root Extract, Camellia Sinensis Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Rosmarinus Officinalis (Rosemary) Leaf Extract, Chamomilla Recutita (Matricaria) Flower Extract, Bioflavonoids, Brassica Oleracea Italica (Broccoli) Extract, *Limonene (essential oil component)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



METABOLIC BRIGHTENING BB CUSHION

titanium dioxide, zinc oxide, alpha bisabolol powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82450-010
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	11.51 g in 100 mL
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	4.75 g in 100 mL
.ALPHA.-BISABOLOL, (+/-)- (UNII: 36HQN158VC) (.ALPHA.-BISABOLOL, (+/-)- - UNII:36HQN158VC)	.ALPHA.-BISABOLOL, (+/-)-	0.5 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Isoamyl Laurate (UNII: M1SLX00M3M)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82450-010-02	1 in 1 CARTON	12/01/2021	
1	NDC:82450-010-01	15 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
unapproved drug other		12/01/2021	

Labeler - rootsallo Qwell (695495466)

Registrant - rootsallo Qwell (695495466)

Establishment

Name	Address	ID/FEI	Business Operations
Elan Cosmetic Co.,ltd		688204926	manufacture(82450-010)

