

THE ORIENTAL GYEOL GOUN TWO WAY PACT- titanium dioxide, octinoxate, zinc oxide powder

TONYMOLY 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.

ACTIVE INGREDIENT

Active Ingredients: Titanium Dioxide 11.64%, Ethylhexyl Methoxycinnamate 6.00%, Zinc Oxide 2.94%

INACTIVE INGREDIENT

INACTIVE INGREDIENT:

Mica (CI 77019), Talc, Alumina, Silica, Hexyl Laurate, HDI/Trimethylol Hexyllactone Crosspolymer, Dimethicone, Iron Oxides (CI 77492), Diphenyl Dimethicone/Vinyl Diphenyl Dimethicone/Silsesquioxane Crosspolymer, Vinyl Dimethicone/Methicone Silsesquioxane Crosspolymer, Methicone, Magnesium Myristate, Hydrogenated Lecithin, Iron Oxides (CI 77491), Methylparaben, Iron Oxides (CI 77499), Propylparaben, Fragrance(Parfum), Ultramarines (CI 77007), Water, Butylene Glycol, Calcium Carbonate, Hydrolyzed Antler Velvet, Caprylic/Capric Triglyceride, Triethoxycaprylylsilane, Phenoxyethanol, Poria Cocos Extract, Rehmannia Glutinosa Root Extract, Citrus Unshiu Peel Extract, Lithospermum Erythrorhizon Root Extract, Coptis Japonica Root Extract, Glycerin, Trichosanthes Kirilowii Root Extract, Camellia Sinensis Leaf Extract, Zizyphus Jujuba Fruit Extract, Phellodendron Amurense Bark Extract, Rosa Davurica Bud Extract, Ethylhexylglycerin, Ligularia Fishceria Leaf Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Oenothera Biennis (Evening Primrose) Seed Extract, Angelica Gigas Root Extract, Prunus Mume Flower Extract, Atractyloides Japonica Rhizome Extract, Cinnamomum Cassia Bark Extract, Panax Ginseng Root Extract, Paeonia Lactiflora Root Extract, Cnidium Officinale Root Extract, Nelumbo Nucifera Flower Extract, Disodium EDTA, Prunus Mume Fruit Extract, Lactic Acid, Citric Acid

PURPOSE

PURPOSE: SUNSCREEN

WARNINGS

Warnings:

1. In case of having following symptoms after using this, you're advised to stop using it immediately. If you keep using it, the symptoms will get worse and need to consult a dermatologist.
 - 1) In case of having problems such as red rash, swollenness, itching, stimulation during usage.
 - 2) In case of having the same symptoms above on the part you put this product on by direct sunlight.
2. You are banned to use it on the part where you have a scar, eczema, or dermatitis.
3. In case of getting it into your eyes, you have to wash it immediately.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:

Keep out of reach of babies and children

INDICATIONS AND USAGE

titanium dioxide, octinoxate, zinc oxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59078-017
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Titanium Dioxide (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	Titanium Dioxide	2.33 g in 20 g
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.2 g in 20 g
Zinc Oxide (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.59 g in 20 g

Inactive Ingredients

Ingredient Name	Strength
Mica (UNII: V8A1AW0880)	
Talc (UNII: 7SEV7J4R1U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59078-017-01	20 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	10/01/2013	

Labeler - TONYMOLY CO., LTD. (688216798)

Registrant - TONYMOLY CO., LTD. (688216798)

Establishment

Name	Address	ID/FEI	Business Operations
TONYMOLY CO., LTD.		688216798	manufacture(59078-017)

Revised: 8/2013

TONYMOLY CO., LTD.