

WELLAGE POST PROCEDURE POINT CONCEALER - titanium dioxide cream
HUGEL PHARMA 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.

Drug Facts

titanium dioxide

isopropyl myristate, mica candelilla wax, sorbitan olivate ceresin, dimethicone, lanolin, methicone, etc

sun block, skin protectant

keep out of reach of the children

apply proper amount to the skin

☐ Stop using the product when you have skin problems or the product disagrees with your skin

☐ Stop using the product immediately and consult a dermatologist if you have redness, swelling, itching or irritation on the skin while or after using the product.

☐ If the product gets into the eyes, don't rub but rinse with water.

☐ Don't place the product in any place where it will be subjected to extremely high or low temperatures or direct sunlight.

for external use only

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titanium dioxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69346-4001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	TITANIUM DIOXIDE	25 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69346-4001-1	4.8 g in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	12/01/2014	

Labeler - HUGEL PHARMA CO.,LTD (688400184)

Registrant - HUGEL PHARMA CO.,LTD (688400184)

Establishment

Name	Address	ID/FEI	Business Operations
HUGEL PHARMA CO.,LTD		688400184	manufacture(69346-4001)

Revised: 1/2015

HUGEL PHARMA CO.,LTD