

RACHEL K MINERAL CC PRESSED- titanium dioxide powder
RACHEL K COSMETICS PTE. 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 ingredient: TITANIUM DIOXIDE 7%

INACTIVE INGREDIENT

Inactive ingredients:

MICA, KAOLIN, CAPRYLIC/CAPRIC TRIGLYCERIDE, ZINC STEARATE, SILICA, IRON OXIDE YELLOW, IRON OXIDE RED, DIISOSTEARYL MALATE, HYDROGENATED LECITHIN, IRON OXIDE BLACK, DIMETHICONE, TRIETHOXYCAPRYLYLSILANE, METHYLPARABEN, BUTYLPARABEN, ALLANTOIN, TOCOPHERYL ACETATE, BUTYROSPERMUM PARKII (SHEA BUTTER)

PURPOSE

Purpose: Sunscreen

WARNINGS

Caution:

For external use only.

Do not swallow.

Keep out of reach of children.

Avoid contact with eyes.

Do not store it in extreme high or low temperatures.

KEEP OUT OF REACH OF CHILDREN

KEEP OUT OF REACH OF CHILDREN

INDICATIONS AND USAGE

HOW TO USE:

Apply with Powder Brush or included sponge applicator.

Can be used all over face, or just on oily spots.

DOSAGE AND ADMINISTRATION

HOW TO USE:

Apply with Powder Brush or included sponge applicator.

Can be used all over face, or just on oily spots.

PACKAGE LABEL. PRINCIPAL DISPLAY PANEL



RACHEL K MINERAL CC PRESSED

titanium dioxide powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53241-020
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	0.84 g in 12 g

Inactive Ingredients

Ingredient Name	Strength
KAOLIN (UNII: 24H4NWX5CO)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ZINC STEARATE (UNII: H92E6QA4FV)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53241-020-01	12 g in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	01/15/2012	

Labeler - RACHEL K COSMETICS PTE. LTD. (595309583)**Registrant** - RACHEL K COSMETICS PTE. LTD. (595309583)**Establishment**

Name	Address	ID/FEI	Business Operations
RACHEL K COSMETICS PTE. LTD.		595309583	manufacture(53241-020)

Revised: 9/2012

RACHEL K COSMETICS PTE. LTD.