

HYDRA INTENSIVE BLEMISH BALM SPF30 PA - titanium dioxide octinoxate zinc oxide cream

The Doctor's Cosmetic Inc

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 INGREDIENTS:

Titanium Dioxide, Ethylhexyl Methoxycinnamate, Zinc Oxide, Rosmarinus Officinalis (Rosemary) Leaf Oil, Portulaca Oleracea Extract, Citrus Grandis (Grapefruit) Peel Extract, Camellia Sinensis Leaf Extract

CAUTION: Keep away from children.

DIRECTION OF USE:

Apply thin layer of blemish balm onto all over the face. Use fingertips to spread gently until it has been completely absorbed.

Label18c



HYDRA INTENSIVE BLEMISH BALM SPF30 PA

titanium dioxide octinoxate zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:43948-7001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM - UNII:D1JT611TNE)	TITANIUM DIOXIDE	3 mL in 60 mL
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	1.8 mL in 60 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC - UNII:J41CSQ7QDS)	ZINC OXIDE	0.3 mL in 60 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43948-7001-1	60 mL in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/01/2009	

Labeler - The Doctor's Cosmetic Inc (687479378)

Registrant - The Doctor's Cosmetic Inc (687479378)

Establishment

Name	Address	ID/FEI	Business Operations
The Doctor's Cosmetic Inc		687479378	manufacture

Revised: 10/2009

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