

SUNSCREEN- sunscreen lotion ointment
Private Label Select Ltd CO

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

Active ingredient	Purpose
Zinc Oxide 20%	Sunscreen

Uses

- helps prevent sunburn
- if used as directed with other sun protection measures (see Directions) decreases the risk of skin cancer and early skin aging caused by the sun

Warnings
For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove

Stop use and ask doctor if rash occurs

Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away

Directions

- apply liberally 15 minutes before sun exposure
- reapply:
 - after 60 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours
- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. to 2 p.m.
 - wear long sleeve shirts, pants, hats and sunglasses
 - children under 6 months: Ask a doctor

Other information
protect this product from excessive heat and direct sun

Inactive ingredients
Helianthus Annuus (Sunflower) Seed Oil, Cera Alba (Beeswax), Ricinus Communis (Castor) Seed Oil, Cocos Nucifera (Coconut) Oil, Olea Europaea (Olive) Fruit Oil, Simmondsia Chinensis (Jojoba) Oil, Butyrospermum Parkii (Shea) Butter, Tocopherol

Questions? www.ems.com

SUNSCREEN

sunscreen lotion ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62932-165
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
SUNFLOWER OIL (UNII: 3W1JG795YI)	
SHEA BUTTER (UNII: K49155WL9Y)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
JOJOBA OIL (UNII: 724GKU717M)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
CASTOR OIL (UNII: D5340Y2I9G)	
COCONUT OIL (UNII: Q9L0O73W7L)	
TOCOPHEROL (UNII: R0ZB2556P8)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-165-20	84 g in 1 TUBE; Type 0: Not a Combination Product	05/07/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/07/2018	

Labeler - Private Label Select Ltd CO (005415463)**Registrant** - Private Label Select Ltd CO (005415463)**Establishment**

Name	Address	ID/FEI	Business Operations
Private Label Select Ltd CO		005415463	manufacture(62932-165)