

**EMMA LEWISHAM SUNCEUTICAL SPF 50 MINERAL FACE CREAM- zinc oxide
20% lotion
EMMA LEWISHAM US, INC.**

Drug Facts

Active Ingredient

Zinc Oxide 20%

Purpose

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 a 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
- Children under 6 months of age: Ask a doctor
- **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 value of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. -2 p.m.
 - Wear long-sleeved shirts, pants, hats, and sunglasses
 - Reapply at least every 2 hours
 - Use a water resistant sunscreen if swimming or sweating

Other information

- Protect the product in this container from excessive heat and direct sun

Inactive Ingredients

Water, Coco-Caprylate/Caprate, Isohexadecane, Caprylic/Capric Triglyceride, Coco-Caprylate, Polyglyceryl-2 Dipolyhydroxystearate, Isoamyl Laurate, Pentylene Glycol, Isododecane, Polyglyceryl-3 Polyricinoleate, Glyceryl Polymethacrylate, Polyglyceryl-3 Diisostearate, Sorbitan Olivatate, Magnesium Sulfate, Niacinamide, Polyhydroxystearic Acid, Saccharide Isomerate, Isostearic Acid, Fragrance, Distearidimonium Hectorite, Hydroxyacetophenone, Propylene Glycol, Pongamia Pinnata Seed Extract, Propylene Carbonate, Iron Oxides, Limonene, Citric Acid, Sodium Citrate, Linalool, Palmitoyl Tripeptide-1

PRINCIPAL DISPLAY PANEL

EMMA LEWISHAM

Sunceutical SPF 50 Mineral Face Cream

ZINC OXIDE MINERAL SUN-ACTIVE

BROAD SPECTRUM SPF 50 SUNSCREEN

50 mL/1.7 FL. OZ.

Emma Lewisham
Sunceutical SPF 50 Mineral Face Creme
Main Carton
[US]



PMS 2367 C



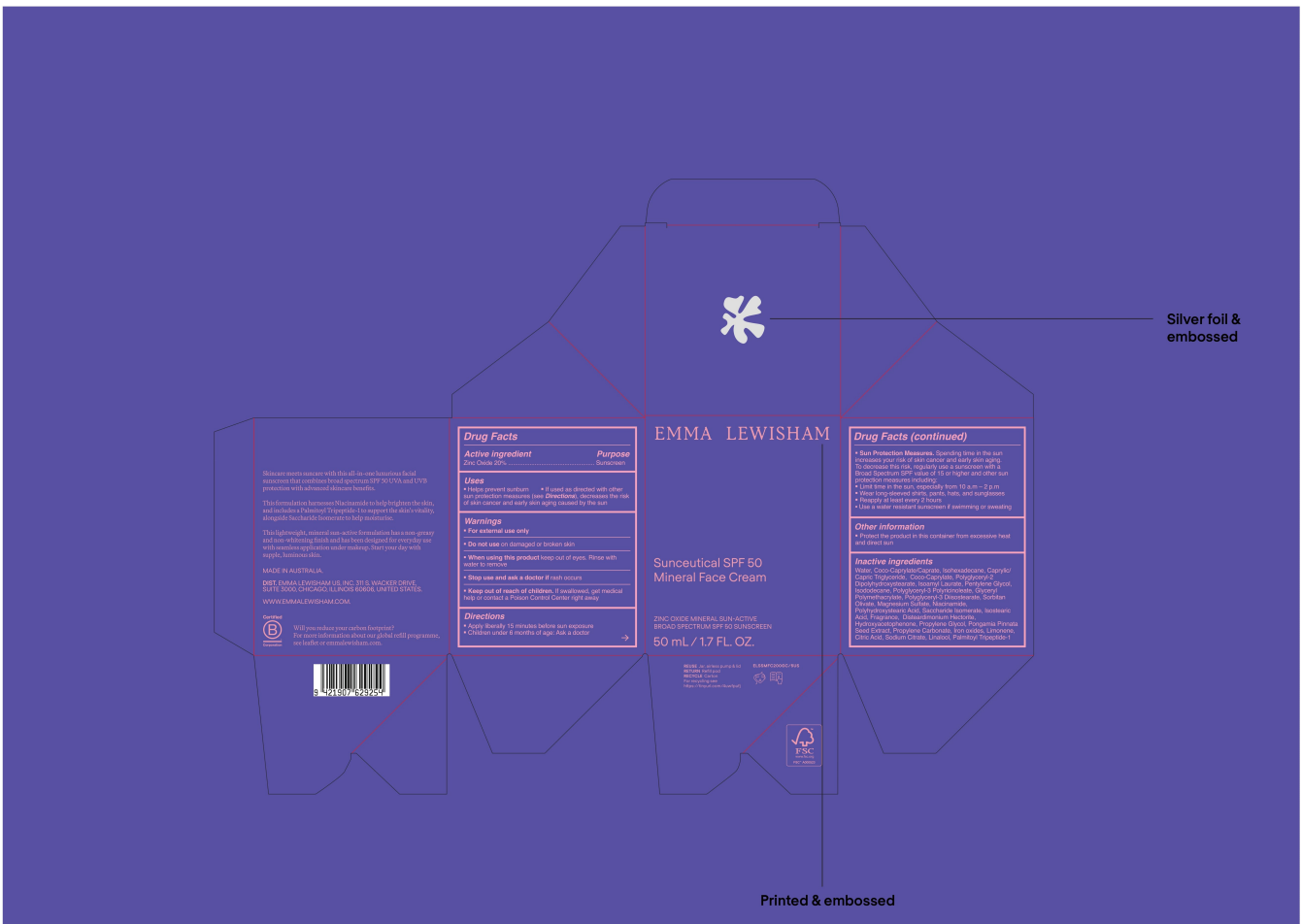
PMS 197 C



Silver foil

TO SCALE

Carton outer + inner to be Purple PMS 2367C



Emma Lewisham
Sunceutical SPF 50 Mineral Face Creme
Refill Carton
[US]

Carton outer & inner to be purple PMS 2367C



Background:
PMS 2367 C
on soft touch
matte stock

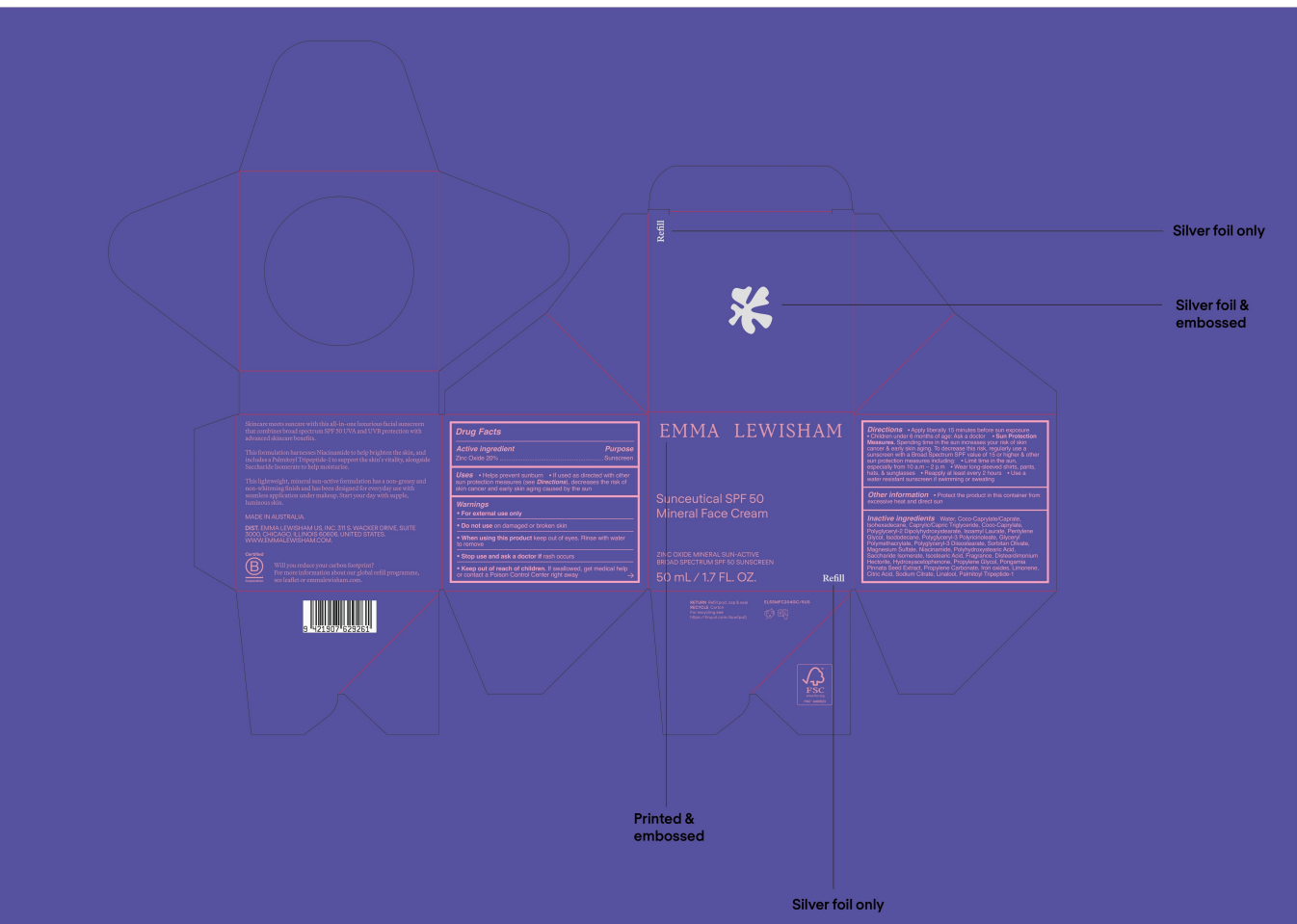


Artwork:
PMS 197 C



Motif & 'Refill':
Silver foil
embossed

TO SCALE



Emma Lewisham
Sunceutical SPF 50 Mineral Face Creme
50ml airless jar
[US]



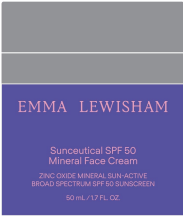
Jar:
PMS 2367 C



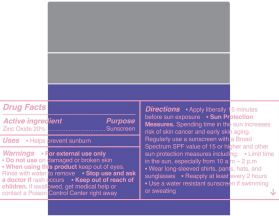
Artwork:
PMS 189 C

TO SCALE

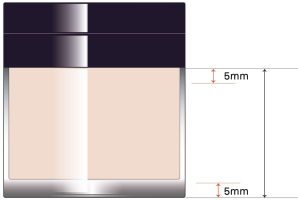
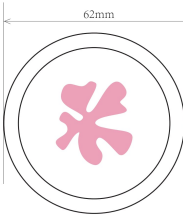
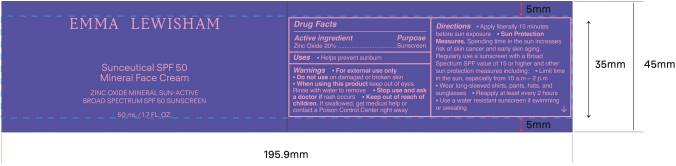
Front



Back

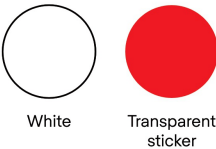


Print area



Sunceutical SPF 50 Mineral Face Cream
ZINC OXIDE MINERAL SUN-ACTIVE
BROAD SPECTRUM SPF 50 SUNSCREEN
50 mL/1.7 FL. OZ.

Emma Lewisham
[US] Sunceutical SPF 50 Face Cream
Refill pod sticker for refill SKU's only



TO SCALE

Sticker maximum print area: 155mm x 27mm
Sticker actual size: 100mm x 26mm



EMMA LEWISHAM SUNCEUTICAL SPF 50 MINERAL FACE CREAM
zinc oxide 20% lotion

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84981-005
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 mL
Inactive Ingredients			
Ingredient Name			Strength
SORBITAN OLIVATE (UNII: MDL271E3GR)			
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)			
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			

POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q0OK5DOT4)	
PROPYLENE CARBONATE (UNII: 8D08K3S51E)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
GLYCERYL POLYMETHACRYLATE (300000 MPA.S) (UNII: 2B25A5KAD6)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
LEMON TERPENES (UNII: 5DHA4TVW63)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
MAGNESIUM SULFATE (UNII: DE08037SAB)	
ISOCYCLEMONE E (UNII: 1GD7ODM28Y)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
LINALOOL (UNII: D81QY6I88E)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
COCO-CAPRYLATE (UNII: 4828G836N6)	
ISOSTEARIC ACID (UNII: X33R8U0062)	
WATER (UNII: 059QF0KO0R)	
POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
ISODODECANE (UNII: A8289P68Y2)	
NIACINAMIDE (UNII: 25X51I8RD4)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PONGAMIA PINNATA SEED (UNII: C2BRV53B1V)	
LINALYL ACETATE (UNII: 5K47SSQ51G)	
DISTEARDIMONIUM HECTORITE (UNII: X687XDK09L)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
CITRIC ACID (UNII: 2968PHW8QP)	
PALMITOYL TRIPEPTIDE-1 (UNII: RV743D216M)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
HEXAMETHYLINDANOPYRAN (UNII: 14170060AT)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84981-005-01	1 in 1 CARTON	06/01/2025	
1		50 mL in 1 JAR; Type 0: Not a Combination Product		
2	NDC:84981-005-02	1 in 1 CARTON	06/01/2025	
2		50 mL in 1 JAR; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	06/01/2025	

Labeler - EMMA LEWISHAM US, INC. (119326604)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Laboratories Pty. Ltd.		740537709	manufacture(84981-005)

Revised: 2/2025

EMMA LEWISHAM US, INC.