SOMBRA MAX- sombra max cream
Sombra Cosmetics Inc.

Active Ingredients Section OTC

Methyl Salicylate 12%

Menthol USP 6%

Camphor USP 3%

Capsaicin 0.025%

Histamine Dihydrochloride 0.025%

Purpose

Purpose

External Analgesic

Uses

Temporarily relieves minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, sprains

Warnings

For external use only. Do not use if allergic to salicylates (including aspirin), on wounds or damaged skin or with a heat source. When using this product: avoid bandaging tightly, avoid contact with eyes, keep out of reach of children. If swallowed, get medical help or contact a Posion Control Center right away.

Stop use and ask doctor if: condition worsens, symptoms persist for more than 7 days, clear up and occur again within a few days.

Keep out of reach of children

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

Directions

Directions: adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily, rub in thoroughly until gel is absorbed, children under 2 years of age: consult a doctor.

Inactive Ingredients

Inactive Ingredients: Aloe Barbadensis Leaf Extract, Carbomer, Cetearyl Alcohol, Cetyl Esters, Caprylyl Glycol, Glycerin, Phenoxyethanol, Polysorbate 60, Purified Water, Sodium Carbonate, Stearic Acid, Tocopheryl Acetate (Vitamin E), Yucca Schidigera Stem Extract.

Questions

1-800-225-3963

Sombra Max Package Label Principal Display Panel

SOMBRA MAX

sombra max cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61577-3440
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL GLUCURONIDE (UNII: WW64GZ6LQY) (MENTHOL GLUCURONIDE - UNII:WW64GZ6LQY)	MENTHOL GLUCURONIDE	6 g in 100 g
HISTAMINE DIHYDROCHLORIDE (UNII: 3POA0Q644U) (HISTAMINE - UNII:820484N8I3)	HISTAMINE DIHYDROCHLORIDE	0.025 g in 100 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	3 g in 100 g
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	12 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ESTERS (UNII: D072FFP9GU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61577-3440-1	1 g in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2026	
2	NDC:61577-3440-2	1 g in 1 PACKET; Type 0: Not a Combination Product	01/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	01/01/2026	

Labeler - Sombra Cosmetics Inc. (097464309)

Establishment

Name	Address	ID/FEI	Business Operations
Sombra Cosmetics Inc.		097464309	manufacture(61577-3440)

Revised: 10/2025 Sombra Cosmetics Inc.