

HIELO MINERAL- external analgesic liquid
I Shay Cosmetics Inc

Topical Analgesic Spray

Active Ingredient

Menthol 2%..... Topical Analgesic

Camphor 3%..... Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains. Cooling pain relief.

WARNINGS - Keep out of reach of children

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains. Cooling pain relief.

Inactive Ingredients

Ethanol, Water, Methyl Salicylate, Hydrogenated Castor Oil, FD&C Blue No. 1.

Warnings

For external use only

Avoid contact with eyes

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

Do not apply to wounds or damaged skin

Do not bandage tightly

If pregnant or breast-feeding, ask a health professional before use

Keep out of reach of children

If swallowed, get medical help or contact a poison control center right away

DIRECTIONS

Adults and children 2 years of age and older: Spray to affected area not more than 3 to 4 times daily. Leave it on.

Children under 2 years of age: Consult a physician

Other Information

Store at room temperature between 15 °and 30°C (59°-86°F)

label

HIELO MINERAL

external analgesic liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65112-261
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.02 g in 1 g
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	0.03 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	0.18 g in 1 g
ALCOHOL (UNII: 3K9958V90M)	0.65 g in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65112-261-01	254 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	01/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		01/13/2021	

Labeler - I Shay Cosmetics Inc (151582384)

Revised: 10/2022

I Shay Cosmetics Inc