

SHELO NABEL HIELO MINERAL- menthol spray
Corporativo Serysi S de R L de C V

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.

Sheló NABEL Hielo Mineral Topical Analgesic Spray

Active Ingredient U060

Active Ingredient

Purpose

Menthol 1.25%	Topical Analgesic
Camphor 0.2%	Topical Analgesic

Inactive Ingredient

Inactive Ingredients

Ethanol, Water, Methyl Salicylate, Hydrogenated Castor Oil.

Warnings

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

KROC U060

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Uses U060

Use ■ 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.

Administration

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.

Indications U060

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.

Display Panel



Hielo Mineral

TOPICAL ANALGESIC SPRAY
Menthol 1.25%, Camphor 0.2%

**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.**

Made in Mexico

NET CONTENTS 8.7 fl oz / 260 ml

SHELO NABEL HIELO MINERAL

menthol spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71424-1060
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2 mg in 1 g
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	12.5 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
DIMETHYL SALICYLATE (UNII: SB18J2MCQL)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71424-1060-1	260 g in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/18/2017	

Labeler - Corporativo Serysi S de RL de C V (816628390)**Registrant** - Corporativo Serysi S de RL de C V (816628390)