SHELO NABEL ARNICA GEL- menthol gel
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 Árnica Gel

Active Ingredient U058

Active Ingredient	Purpose
Menthol 1.25%	Topical Analgesic

Inactive Ingredient U058

Inactive ingredients Distilled Water, Ethanol, Propylene Glycol, Polysorbate 20, Carbomer 940, Triethanolamine, Arnica Extract, FD&C Yellow No. 5.

Warnings U058

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 U058

Keep out of reach of children

Administration U058

Directions ▪ Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily. Gently massage the area until absorbed. ▪ Children under 2 years of age: Consult a physician.

Indications U058

FOR THE TEMPORARY RELIEF OF MINOR ACHES AND PAINS OF MUSCLES AND JOINTS ASSOCIATED WITH SIMPLE BACKACHE, ARTHRITIS, STRAINS, BRUISES AND SPRAINS.

Uses U058

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

Display Panel U058

ÁRNICA

TOPICAL ANALGESIC GEL
MENTHOL 1.25%

FOR THE TEMPORARY RELIEF OF MINOR ACHES AND PAINS OF MUSCLES AND JOINTS ASSOCIATED WITH SIMPLE BACKACHE, ARTHRITIS, STRAINS, BRUISES AND SPRAINS.

SHELO NABEL ARNICA GEL

menthol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71424-1058
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	12.5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
POLYSORBATE 20 (UNII: 7T1F30V5YH)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71424-1058-1	250 g in 1 BOTTLE, DISPENSING; 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 R L de C V (816628390)

Registrant - Corporativo Serysi S de R L de C V (816628390)

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