

LABELLA LINIMENTO OBRERO- capsaicin, menthol, unspecified form, and methyl salicylate cream

Golden Sun Inc DBA Newhall Laboratories

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.

LaBella™ Linimento Obrero

Drug Facts

Active Ingredients	Purpose
Capsaicin 0.025%	Topical Analgesic
Menthol 2.0%	Topical Analgesic
Methyl Salicylate 10%	Topical Analgesic

Use

- Temporarily relieves the minor aches and pains of muscle and joints.

Warnings

- For external use only.
- Keep this and all other drugs out of the reach of children.
- If swallowed, get medical help or contact a Poison Control Center immediately.

When using this product

- Avoid contact with eyes.
- Do not bandage tightly.
- Do not apply to wounds or broken skin.
- If condition worsens or if symptoms persist for more than 7 days, discontinue use of this product and consult a physician.

Directions

- Use only as directed.
- Adults and children 2 years of age or older: apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: consult a physician.

Inactive Ingredients

Water (Aqua), Stearic Acid, Isopropyl Palmitate, Propylene Glycol, Cetyl Alcohol, Glyceryl Monostearate, Thiethanolamine, Stearyl Alcohol, Polysorbate 60, Phenoxyethanol, Carbomer, Methylparaben, Propylparaben, Sorbitan Sesquioleate, Tetra Sodium EDTA.

Questions?

www.labellabeauty.com

Distributed by

Newhall Laboratories, Inc.
5 High Ridge Park, Suite 100
Stamford, CT 06905

PRINCIPAL DISPLAY PANEL - 236 ml Bottle Label

LA BELLA™

LINIMENTO

OBRERO

Pain Relieving Cream
with Chile Extract

Relieves minor aches & pains

Net Wt. 8 FL. OZ. (236 ml)

LA BELLA™

**LINIMENTO
OBRERO**

con Extracto de Chile

Alivia malestares y dolores menores



**Pain Relieving Cream
with Chile Extract**

Relieves minor aches & pains

Net Wt. 8 FL. OZ. (236 ml)

LA BELLA™

**PAIN RELIEVING CREAM
WITH CHILE EXTRACT**

This unique cream temporarily relieves minor muscle and joint pain associated with everyday work or sport activities.

LINIMENTO OBRERO CON EXTRACTO DE CHILE
Esta crema exclusiva alivia temporalmente los dolores menores de músculos y articulaciones causados por el trabajo diario o actividades deportivas. **Advertencias:** Solamente para el uso externo. Evita el contacto con los ojos.

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Questions? www.labelbeauty.com



Made in the USA.
Distributed by
Newhall Laboratories, Inc.
5 High Ridge Park, Suite 100
Stamford, CT 06906
LB80050

LABELLA LINIMENTO OBRERO

capsaicin, menthol, unspecified form, and methyl salicylate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:31774-8005
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.25 mg in 1 mL
Menthol, Unspecified Form (UNII: L7T10EIP3A) (Menthol, Unspecified Form - UNII:L7T10EIP3A)	Menthol, Unspecified Form	20 mg in 1 mL
Methyl Salicylate (UNII: LAV5U5022Y) (Salicylic Acid - UNII:O414PZ4LPZ)	Methyl Salicylate	100 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Isopropyl Palmitate (UNII: 8CRQ2TH63M)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Cetyl Alcohol (UNII: 936JST6JCN)	
Glyceryl Monostearate (UNII: 230OU9XXE4)	
Stearyl Alcohol (UNII: 2KR89I4H1Y)	
Polysorbate 60 (UNII: CAL22UVI4M)	
Phenoxyethanol (UNII: HIE492ZZ3T)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Sorbitan Sesquioleate (UNII: 0W8RR5W5A)	
Edetate Sodium (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:31774-8005-1	236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part346	01/02/2013	

Labeler - Golden Sun Inc DBA Newhall Laboratories (060383791)

Revised: 11/2015

Golden Sun Inc DBA Newhall Laboratories