

**MIRACLE PLUS OVERNIGHT PAIN RELIEVING- capsaicin gel**  
**Concept Laboratories, Inc.**

*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.*

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**Miracle<sup>®</sup> Plus Overnight**  
**Pain Relieving Gel**

Drug Facts

**Active ingredient**

Capsicum Oleoresin 0.0625% (Containing Capsaicin 0.025%)

**Purpose**

Pain Relieving

**Uses**

for the temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
- arthritis
- strains
- sprains
- bruises

**Warnings**

For external use only.

- do not apply to wounds or damaged skin
- do not bandage tightly
  
- Do not use with heating pad, wrap, hot water bottle or any heating element.

When using this product do not get into eyes

- avoid contact with other mucous membranes

Discontinue 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

Keep out of reach of children.

- if swallowed, get medical help or contact a Poison Control center right away
  
- if pregnant or nursing, seek the advice of a health professional before using

**Directions**

- Children under 12 years of age consult a physician
- Apply a thin layer to affected area not more than 3 to 4 times daily
- Gently massage into the skin until fully absorbed
- Wash hands with soap and water after each application to avoid spreading to the eyes or other

sensitive mucous membranes

### **Other information**

- It is recommended to test for skin sensitivity prior to use. Apply product to a small area, follow the directions and wait 24 hours. Proceed with application if no adverse reaction.
- A burning sensation may occur upon initial application but generally disappears with continued use. For a severe burning discomfort, remove excess product with a soft cloth and cooking oil.
- If applying product to hands, wait 30 minutes before washing.
- Avoid water, heat, or direct sunlight while using product.
- If wearing contact lenses, insert prior to application and avoid touching them after applying product.
- If eye contact occurs, flush immediately with water.

### **Inactive ingredients**

Water (Aqua), Glycerin, PEG-75 Lanolin, Aloe Barbadosensis Leaf Juice, PEG-40 Hydrogenated Castor Oil, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Triethanolamine, Polysorbate 20, Glucosamine HCl, Emu Oil, Dimethyl Sulfone, Celosia Argentea Seed Extract, Ginkgo Biloba Extract, Panax Ginseng Root Extract, Medicago Sativa (Alfalfa) Extract, Cymbopogon Schoenanthus Extract, Tocopheryl Acetate, DMDM Hydantoin, Propylene Glycol, Methylparaben, Propylparaben.

### **Questions or comments?**

Call 1-888-373-8831 or visit [www.conceptlabs.org](http://www.conceptlabs.org)

Manufactured by Concept Laboratories, Inc., Chicago, IL 60642 #BG-MP9874

### **PRINCIPAL DISPLAY PANEL - 113 g Bottle Label**

**MIRACLE®  
PLUS**

**OVERNIGHT**

**PAIN RELIEVING  
GEL**

odor-free  
pain relief

**IMMEDIATE  
RELIEF**

- **Warming, soothing pain relief**
- **Stainless, greaseless formula**
- **Temporarily relieves backaches,  
muscle aches, joint pain, and arthritis**

**4 OZ. (113 g)**



# OVERNIGHT

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## MIRACLE PLUS OVERNIGHT PAIN RELIEVING

capsaicin gel

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64058-155
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Capsaicin (UNII: S07O44R1ZM) (Capsaicin - UNII:S07O44R1ZM)	Capsaicin	0.02825 g in 113 g

### Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Glycerin (UNII: PDC6A3C0OX)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	

<b>DIMETHYL SULFONE</b> (UNII: 9H4PO4Z4FT)
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>ALFALFA LEAF</b> (UNII: HY3L927V6M)
<b>CYMOPOGON SCHOENANTHUS LEAF</b> (UNII: XF54B1Z2HF)
<b>GLUCOSAMINE HYDROCHLORIDE</b> (UNII: 750W5330FY)
<b>GINKGO</b> (UNII: 19FUJ2C58T)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>EMU OIL</b> (UNII: 344821WD61)
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)
<b>ASIAN GINSENG</b> (UNII: CUQ3A77YXI)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>POLYOXYL 40 HYDROGENATED CASTOR OIL</b> (UNII: 7YC686GQ8F)
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)

<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64058-155-44	113 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:64058-155-42	57 g in 1 BOTTLE; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	11/20/2014	

**Labeler** - Concept Laboratories, Inc. (962282612)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
Concept Laboratories, Inc.		962282612	MANUFACTURE(64058-155)