

PAIN RELIEF SLEEVE LARGE- menthol patch
PAIN RELIEF SLEEVE EXTRA LARGE- menthol patch
PAIN RELIEF SLEEVE MEDIUM- menthol patch
Great Lakes Wholesale, Marketing, and Sales, 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.

Menthol 16.0%

Topical Analgesic Patch

For temporary relief of minor aches and pains of muscles and joints associated with:

- arthritis
- strains
- bruises
- sprains

For external use only

When using this product:

- avoid contact with eyes
- do not apply to wounds or damaged skin
- do not bandage tightly
- do not use with heating pad

Stop using and ask a doctor

if redness is present or irritation develops. Condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

If swallowed, get medical help or contact a Poison Control Center immediately

- Adults and children over 12 years: pull sleeve onto knee or large ankles or elbows until the colored section of the sleeve is positioned directly over the affected area. Sleeve should feel snug, but not tight.
- Children 12 years or younger: consult a doctor

diethylene glycol monoethyl ether acetate, cetanol, glycerol, glycerol monostearate, methylparaben, 2(2-aminoethoxy) ethanol, sorbitan sesquiolate, sodium polyacrylate, polysorbate 80, aloe barbadensis leaf extract, methyl orange-xylene cyanol solution, ethylenediaminetetracetic acid tetrasodium salt hydrate.

NDC 64092-506-1, ITEM 863906

GLS

Personal Care Solutions

Extra Strength

Menthol 16%

Pain Relief Sleeve

KNEE & Small-Medium ankles & elbows

Medicated Sleeve

Pain relieving Lotion on a Breathable Sleeve

Medium

Ideal for KNEE

EXPANDS TO FIT 5" TO 12" (12.5cm to 30.5cm)

IN CIRCUMFERENCE

Contains 1 Sleeve Patch

KNEE

- ELBOT
- ANKLE
- WRIST

NDC 64092-520-1, ITEM 863920

GLS

Personal Care Solutions

Extra Strength

Menthol 16%

Pain Relief Sleeve

KNEE & Large Ankles & Elbows

Medicated Sleeve

Pain relieving Lotion on a Breathable Sleeve

Large Sleeve

Ideal for KNEE

EXPANDS TO FIT 8" TO 24" (20 CM TO 61 CM)

IN CIRCUMFERENCE

Contains 1 Sleeve Patch

KNEE

- ELBOW
- ANKLE
- WRIST

NDC 64092-520-1, ITEM 863920

GLS

Personal Care Solutions

Extra Strength

Menthol 16%

Pain Relief Sleeve

KNEE & Large Ankles & Elbows

Medicated Sleeve

Pain relieving Lotion on a Breathable Sleeve

XLarge Sleeve

Ideal for KNEE

EXPANDS TO FIT 12" TO 28" (30.5 CM to 70 CM)

IN CIRCUMFERENCE

Contains 1 Sleeve Patch

KNEE

ELBOW

ANKLE

WRIST

Adults and children over 12 years: pull sleeve onto knee or large ankle or elbow until the colored section of the sleeve is positioned directly over the affected area. sleeve should feel snug, but not tight.





PERSONAL CARE SOLUTIONS™

Drug Facts

Active Ingredient Menthol 16.0% **Purpose** ...Topical Analgesic Patch

Uses For the temporary relief of minor aches and pains of muscles and joints associated with
• arthritis • strains • bruises • sprains

Warnings
For external use only

When using this product
• avoid contact with eyes • do not apply to wounds or damaged skin • do not bandage tightly
• do not use with heating pad

Stop using and ask a doctor if redness is present or irritation develops, 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 immediately.

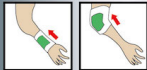
Directions

- Adults and children over 12 years: pull sleeve onto knee or large ankles or elbows until the colored section of the sleeve is positioned directly over the affected area. Sleeve should feel snug but not tight. Apply one sleeve to affected area; not more than 4 times daily.
- Children 12 years or younger: consult a doctor

Inactive ingredients

diethylene glycol monoethyl ether acetate, cetanol, castor oil, glycerol, glycerol monostearate, methylparaben, 2(2-aminoethoxy) ethanol, sorbitan sesquiosulfate, sodium polyacrylate, polysorbate 80, aloe barbadensis leaf extract, methyl orange-xylene cyanol solution, ethylenediaminetetraacetic acid tetrasodium salt hydrate

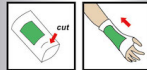
ELBOW



ANKLE



WRIST



Manufactured Exclusively For
Great Lakes Wholesale Group
Bolingbrook, IL 60440
Made in China ©2016
/ Fabriqué en Chine



visit us at www.glw wholesale.com

LOT

EXP

Extra Strength Menthol / Extra puissant Au menthol
PAIN RELIEF SLEEVE / Manchon anti-douleur



#863920
NDC 64092-520-01

Menthol 16% / Menthol 16%



Extra Strength / Extra puissant

**Menthol / Au menthol
Pain Relief Sleeve
/ Manchon anti-douleur**

KNEE / GENOU & Large Ankles & Elbows
et grande chevilles et coudes

Medicated Sleeve
Pain Relieving Lotion on a Breathable Sleeve
/ Lotion anti-douleur sur un manchon respirable



LARGE SLEEVE / Grande manchon
Ideal for KNEE

EXPANDS TO FIT 8" TO 24" (20 CM TO 61 CM)
IN CIRCUMFERENCE / Peut s'étirer de 8" à 24"
(20 cm à 61 cm) de circonférence

Contains 1 Sleeve Patch / Contient un manchon

Extra Strength Menthol / Extra puissant Au menthol
PAIN RELIEF SLEEVE / Manchon anti-douleur



• ELBOW
• ANKLE
• WRIST

Extra Strength Menthol / Extra puissant Au menthol
PAIN RELIEF SLEEVE / Manchon anti-douleur



• ELBOW
• ANKLE
• WRIST



PAIN RELIEF SLEEVE LARGE

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-520
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EP3A) (MENTHOL - UNII:L7T10EP3A)	MENTHOL	160 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	

POLYSORBATE 80 (UNII: 6OZP39ZG8H)
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)
CETYL ALCOHOL (UNII: 936JST6JCN)
MONOETHANOLAMINE (UNII: 5KV86114PT)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
METHYL ORANGE (UNII: 6B4TC34456)
EDETIC ACID (UNII: 9G34HU7RV0)
SOLASULFONE (UNII: H12JE4313S)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-520-01	5 mL in 1 PATCH; Type 0: Not a Combination Product	12/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/05/2016	

PAIN RELIEF SLEEVE EXTRA LARGE

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-544
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	160 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL ORANGE (UNII: 6B4TC34456)	
EDETIC ACID (UNII: 9G34HU7RV0)	
SOLASULFONE (UNII: H12JE4313S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-544-01	5 mL in 1 PATCH; Type 0: Not a Combination Product	12/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/05/2016	

PAIN RELIEF SLEEVE MEDIUM

menthol patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:64092-506
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	160 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A)	
SODIUM POLYACRYLATE (250000 MW) (UNII: 05115JN12J)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
MONOETHANOLAMINE (UNII: 5KV86114PT)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL ORANGE (UNII: 6B4TC34456)	
EDETIC ACID (UNII: 9G34HU7RV0)	
SOLASULFONE (UNII: H12JE4313S)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:64092-506-01	5 mL in 1 PATCH; Type 0: Not a Combination Product	12/05/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/05/2016	

Labeler - Great Lakes Wholesale, Marketing, and Sales, Inc (361925498)

Registrant - Illinois Industrial Tool, Inc (628032898)

Establishment

Name	Address	ID/FEI	Business Operations
Planet (Suzhou) Medical Products Co., Ltd		528194366	manufacture(64092-506, 64092-520, 64092-544)

Revised: 12/2016

Great Lakes Wholesale, Marketing, and Sales, Inc