

WALGREENS COLD PAIN RELIEF- menthol gel

Walgreens, Co

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.

Walgreens Cold Pain Relief Gel

Drug Facts

Active Ingredients

Menthol 4%

Purpose

Cooling Pain Relief

Uses:

Temporary relief from minor aches and pains of sore muscles and joints associated with • arthritis • backache • strains • sprains

Warnings:

For external use only.

Ask a doctor before use if you have:

Sensitive skin

When using this product:

• Avoid contact with the eyes or mucous membranes • Do not apply to wounds or damaged skin • Do not use with other ointments, creams, sprays, or liniments • Do not apply to irritated skin or if excessive irritation develops • Do not bandage • Wash hands after use with cool water • Do not use with heating pad or device • Store in a cool dry place.

Stop use and ask a doctor if:

Condition worsens, or if symptoms persist for more than 7 days, or clear up and recur.

If pregnant or breast-feeding:

Ask a health professional before use

Keep out of reach of children:

If accidentally ingested, get medical help or contact a Poison Control Center immediately.

Directions

- **Adults and Children 2 years of age and older:** rub a thin film over affected areas not more than four times daily; massage not necessary.
- **Children under 2 years of age:** Consult physician

Inactive Ingredients

Aloe Barbadosis Leaf Extract, Arctium Lappa Root (Burdock) Extract, Arnica Montana Flower Extract, Blue 1, Boswellia Carterii Resin Extract, Calendula Officinalis Extract, Camellia Sinensis Leaf Extract, Camphor, Carbomer, Glycerin, Ilex Paraguariensis Leaf Extract, Isopropyl Alcohol, Isopropyl Myristate, Melissa Officinalis (Lemon Balm) Leaf Extract, Silica, Tocopheryl Acetate, Triethanolamine, Water, Yellow 5

Questions or Comments:

1-800-925-4733

Package Labeling:



Walgreens Pharmacist Recommended
Walgreens Pharmacist Survey

13943 P09145-R02

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
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ITEM 773201 W10158-0000-L



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*Compare to Biofreeze®
Gel active ingredient*

NDC 0363-0864-03

Cold Therapy Pain Relief

**MENTHOL USP 4% /
COOLING PAIN RELIEF**

GEL

VANISHING SCENT

- For arthritis, back pain,
sore muscles & joints
- Soothing menthol
- Paraben free

3 FL OZ (89 mL)

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|--------------------|---------------------|
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Questions or comments
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REV 0119 ORG0618-F



WALGREENS COLD PAIN RELIEF

menthol gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0864 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 40 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ARCTIUM LAPPA ROOT (UNII: 597E9B3Z3) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| FD&C BLUE NO. 1 (UNII: HBR47K3TBD) | |
| FRANKINCENSE (UNII: R9XLF1R1WM) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B404F) | |
| ISOPROPYL ALCOHOL (UNII: ND2M416302) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| MELISSA OFFICINALIS LEAF (UNII: 50D2ZE9219) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| WATER (UNII: 059QF0K00R) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:0363-0864-03 | 89 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/06/2018 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348 | 02/06/2018 | |

Labeler - Walgreens, Co (008965063)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|------------|------------------------|
| Span Packaging Services LLC | | 11710 1131 | manufacture(0363-0864) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------|---------|-----------|------------------------|
| Cosmetic Essence, LLC | | 825646862 | manufacture(0363-0864) |

Revised: 2/2021

Walgreens, Co