

**MENTHOZEN- methyl salicylate, menthol, capsaicin cream
Proficient Rx LP**

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.

Menthozen Cream

DRUG FACTS:

ACTIVE INGREDIENTS:

Methyl Salicylate 20.00%

Menthol 5.00%

Capsaicin 0.0375%

Topical Analgesic

USES:

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

WARNINGS:

- For external use only.
- Avoid contact with the eyes.
- If condition worsens, or if symptoms persist for more than seven days or clear up and occur again with a few days, discontinue use of this product and consult a physician.

Keep out of reach of children.

If swallowed, consult physician.

Do not apply

- to wounds or damaged skin.
- Do not bandage tightly.

If pregnant or breast feeding,

contact a physician prior to use.

DIRECTIONS:

Adults and children two-years of age or older: Apply to affected area not more than three to four times daily. Children under two-years of age: consult a physician.

OTHER INFORMATION:

Store at room temperature.

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

INACTIVE INGREDIENTS:

Aloe Barbadensis Leaf Extract, Aqua (Deionized Water), Arnica Montana Flower Extract, Boswellia Serrata Extract, Cetyl Alcohol, DMDM Hydantoin, Emulsifying Wax, Ethoxydiglycol, Ethylhexylglycerin, Glyceryl Stearate, Ilex Paraguayensis (Yerba Mate') Extract, Methylsulfonylmethane (MSM), PEG-100 Stearate, Phenoxyethanol, Polysorbate-20, Stearic Acid, Stearyl Alcohol, Triethanolamine, Xanthan Gum, Zemea (Corn) Propanediol.

Package Labeling:

Menthozen 20% / 5% / 0.0375%
120mL (4 fl oz) Cream

Each bottle contains: Methyl Salicylate 20.00% Topical Analgesic / Menthol 5.00% Topical Analgesic / Capsaicin 0.0375% Topical Analgesic

See Box

Product ID: SM015372
Mfr. For: Village Pharma, LLC Agoura Hills, CA 91301
Store at room temperature.

For external use only.
Keep medication out of the reach of children

Lot #:00000
Exp. 00/00/00
SN#MASTER

Menthozen 20% / 5% / 0.0375%
120mL (4 fl oz) Cream
Lot #:00000 SN#MASTER
NDC 71205-153-72 Exp:00/00/00

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MENTHOZEN

methyl salicylate, menthol, capsaicin cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71205-153(NDC:71574-600) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|----------------|
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 200 mg in 1 mL |
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 50 mg in 1 mL |
| CAPSAICIN (UNII: S07Q44B17M) (CAPSAICIN - UNII:S07Q44B17M) | CAPSAICIN | 0.375 mg |

| | | |
|--|-----------|---------|
| CAPSAICIN (UNII: 307044R1Z1M) (CAPSAICIN - UNII:307044R1Z1M) | CAPSAICIN | in 1 mL |
|--|-----------|---------|

| Inactive Ingredients | |
|--|----------|
| Ingredient Name | Strength |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| WATER (UNII: 059QF0KO0R) | |
| ARNICA MONTANA FLOWER (UNII: OZ0E5Y15PZ) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118X02B) | |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| ILEX PARAGUARIENSIS LEAF (UNII: 1Q953B4O4F) | |
| DIMETHYL SULFONE (UNII: 9H4PO4Z4FT) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| STEARYL ALCOHOL (UNII: 2KR8914H1Y) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |

| Packaging | | | | |
|-----------|------------------|---|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:71205-153-72 | 1 in 1 BOX | 11/01/2018 | |
| 1 | | 120 mL in 1 BOTTLE; 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 | part348 | 10/01/2018 | |

Labeler - Proficient Rx LP (079196022)

| Establishment | | | |
|------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Proficient Rx LP | | 079196022 | RELABEL(71205-153) |