

MENTHOZEN HYDROGEL- menthol, capsaicin patch
Proficient Rx LP

Menthozen Hydrogel Patch

DRUG FACTS:

ACTIVE INGREDIENTS:

Menthol 4.00%

Capsaicin 0.03%

External Analgesic

USES:

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

WARNINGS:

For external use only. Use only as directed.

- Avoid contact with eyes and mucous membranes.
- Do not apply to open wounds or damaged skin.

Do not use

- in combination with any external heat source.
- Do not use on irritated or broken skin, or use in combination with any bandage, wrap, stocking or similar device or garment.

Keep out of reach of children.

- Do not use if allergic to Menthol.

Stop use and consult physician

- if symptoms worsen or persist for more than 7 days.
- Stop use if itching or excessive skin irritation occurs.

If pregnant or breast feeding,

- contact physician prior to use

DIRECTIONS:

Adults and children 12-years and over: Apply to affected area; change patch 1-2 times dily.

Children under 12, consult a physician before use.

How to Apply:

Remove patch from backing and apply directly to area of pain.

Do not apply to affected area more than three times daily.

Use only one patch at a time.

Wash hands with soap and water immediately after application.

Reseal pouch containg unused patches.

OTHER INFORMATION:

Store below 25 degrees Celsius. Avoid direct sunlight.

INACTIVE INGREDIENTS:

Aqua (Deionized Water), Sodium Polyacrylate, Glycerol, D-Glucitol, Sodium Cellulose Glycolate, Polysorbate-80, Lemon Oil, Aluminum Glycinate, Methylparaben, EDTA Disodium Salt

Package Labeling:

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

MENTHOZEN HYDROGEL

menthol, capsaicin patch

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:71205-334(NDC:71574-601) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---------------------------|------------------|
| MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 40 mg in 1 g |
| CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM) | CAPSAICIN | 0.3 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | |
| POLYSORBATE 80 (UNII: 6OZP39ZG8H) | |
| LEMON OIL, COLD PRESSED (UNII: I9GRO824LL) | |
| DIHYDROXYALUMINUM AMINOACETATE ANHYDROUS (UNII: 1K713C615K) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:71205-334-05 | 5 in 1 POUCH | 11/20/2020 | |
| 1 | | 1 g in 1 PATCH; Type 0: Not a Combination Product | | |
| 2 | NDC:71205-334-15 | 15 in 1 POUCH | 09/01/2019 | |
| 2 | | 1 g in 1 PATCH; Type 0: Not a Combination Product | | |
| 3 | NDC:71205-334-30 | 30 in 1 POUCH | 09/01/2019 | |
| 3 | | 1 g in 1 PATCH; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing | Application Number or Monograph | Marketing Start | Marketing End |
|-----------|---------------------------------|-----------------|---------------|
|-----------|---------------------------------|-----------------|---------------|

| Category | Citation | Date | Date |
|--------------------|-----------------|-------------|-------------|
| OTC Monograph Drug | M017 | 07/01/2019 | |

Labeler - Proficient Rx LP (079196022)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------|----------------|---------------|--|
| Proficient Rx LP | | 079196022 | REPACK(71205-334) , RELABEL(71205-334) |

Revised: 12/2023

Proficient Rx LP