**PS- menthol gel**
**New Leaf Pharmaceutical, LLC**

*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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**CBD Power Gel Professional**

**CBD Power Gel Professional**


## PS
menthol gel

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:71798-006 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MENTHOL, UNSPECIFIED FORM** (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A) | MENTHOL, UNSPECIFIED FORM | 10.5 g in 10.5 mL |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CALENDULA OFFICINALIS FLOWER** (UNII: P0M7O4Y7YD) | |
| **ISOPROPYL ALCOHOL** (UNII: ND2M416302) | |
| **MAGNESIUM CHLORIDE** (UNII: 02F3473H9O) | |
| **ARNICA MONTANA FLOWER WATER** (UNII: U7L2JP51PR) | |
| **WILLOW BARK** (UNII: S883J9JDYX) | |
| **HYDROXYETHYL CELLULOSE (2000 CPS AT 1%)** (UNII: S38J6RZN16) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | white | **Score** | |
| **Shape** | | **Size** | |
| **Flavor** | | **Imprint Code** | |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:71798-006-03 | 88.7 mL in 1 TUBE; Type 0: Not a Combination Product | 04/01/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 04/01/2020 | |

## Labeler - New Leaf Pharmaceutical, LLC (080792350)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| New Leaf Pharmaceutical, LLC | | 080792350 | manufacture(71798-006) |

Revised: 1/2020 New Leaf Pharmaceutical, LLC