**PROFOOT PAIN RELIEF PATCHES- camphor, menthol, methyl salicylate**
**Profoot, Inc.**

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**Profoot Pain Relief Patches**

**Active ingredients**

Camphor 1.2%

Menthol 5.7%

Methyl salicylate 6.3%

**Purpose**

Topical Analgesic

Topical Analgesic

Topical Analgesic

**Uses** For temporary relief of minor aches & pains of muscles & joints associated with:

•arthritis •strains •bruises •sprains

**Warnings**

**For external use only**

**Allergy alert:** If prone to allergic reaction from aspirin or salicylates, consult a doctor before use.

**Do not use**

• on wounds or damaged skin • with a heating pad • if you are allergic to any of the ingredients of this product

**When using this product**

• use only as directed • avoid contact with the eyes, mucous membranes or rashes • do not bandage tightly

**Stop use and ask a doctor if**

• rash, itching or excessive skin irritation develops • condition worsens •symptoms persist for more than 7 days • symptoms clear up and occur again within a few days

**If pregnant or breastfeeding,** ask a health professional before use.

**Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away

**Directions**

Adults and children 12 years of age and over:

• clean and dry affected area • remove patch from film • apply to affected area not more than 3-4 times daily • remove patch from skin after at most 8 hours

**Children under 12 years of age**: consult a doctor

**Other information**

• avoid storing in direct sunlight • protect product from excessive moisture

**Inactive ingredients** hydrogenated poly, pentaerythrityl tetra-di-t-butyl Hydroxyhydrocinnamate, white mineral oil, styrene/Isoprene copolymer

**Questions or comments?** Email cservice@profoot.co

**PROFOOT PAIN RELIEF PATCHES**
camphor, menthol, methyl salicylate kit

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:29784-601 |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:29784-601-01 | 1 in 1 KIT | 10/12/2023 | |

## Quantity of Parts

| Part # | Package Quantity | Total Product Quantity |
|---|---|---|
| **Part 1** | 1 PATCH | 0.36 g |
| **Part 2** | 1 PATCH | 1.3 g |

# Part 1 of 2

# PROFOOT

camphor, menthol, methyl salicylate patch

## Product Information

| | |
|---|---|
| **Item Code (Source)** | NDC:29784-121 |
| **Route of Administration** | TOPICAL |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **METHYL SALICYLATE** (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 63 mg in 1 g |
| **CAMPHOR (NATURAL)** (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 12 mg in 1 g |
| **MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 57 mg in 1 g |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER** (UNII: K7S96QM8DV) | |
| **PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)** (UNII: 255PIF62MS) | |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **HYDROGENATED C6-20 POLYOLEFIN (100 CST)** (UNII: 39EYQ1W9RB) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | | 1 in 1 KIT | | |
| **1** | NDC:29784-121-36 | 0.36 g in 1 PATCH; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M017 | 10/12/2023 | |

## Part 2 of 2

## PROFOOT

camphor, menthol, methyl salicylate patch

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:29784-122 |
| **Route of Administration** | TOPICAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **CAMPHOR (NATURAL)** (UNII: N20HL7Q941) (CAMPHOR (NATURAL) - UNII:N20HL7Q941) | CAMPHOR (NATURAL) | 12 mg in 1 g |
| **MENTHOL** (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) | MENTHOL | 57 mg in 1 g |
| **METHYL SALICYLATE** (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) | METHYL SALICYLATE | 63 mg in 1 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **MINERAL OIL** (UNII: T5L8T28FGP) | |
| **PENTAERYTHRITOL TETRAKIS(3-(3,5-DI-TERT-BUTYL-4-HYDROXYPHENYL)PROPIONATE)** (UNII: 255PIF62MS) | |
| **HYDROGENATED C6-20 POLYOLEFIN (100 CST)** (UNII: 39EYQ1W9RB) | |
| **STYRENE/ISOPRENE/STYRENE BLOCK COPOLYMER** (UNII: K7S96QM8DV) | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | | 2 in 1 KIT | | |
| **1** | NDC:29784-122-36 | 1.3 g in 1 PATCH; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M017 | 10/12/2023 | |


## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M017 | 10/12/2023 | |


## Labeler - Profoot, Inc. (107570900)

Revised: 10/2023 Profoot, Inc.