MCM TOPICAL GEL PATCH- l-menthol patch
FORREAL PHARMACEUTICALS LLC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

MCM Topical Gel Patch

Drug Facts

Active Ingredients

L-Menthol 76.8mg

Methyl Salicylate 57.6mg

DL-Camphor 96.0mg

Purpose

Topical Analgesic

Uses

For temporary relief of minor aches and pains of muscles and joints associated with:
- Arthritis
- Simple backache
- Strains
- Bruises
- Sprains

Warnings

For external use only

Do not use
- On wounds or damaged skin
- If you are allergic to aspirin or salicylates
- With a heating pad
- With, or at the same time as other external analgesic products

Ask a doctor before use if you are allergic to any ingredients in this product.

When using this product
- Do not use other than directed
- Avoid contact with eyes, mucous membranes, and rashes

Stop use and ask a doctor if

- Rash, itching, or excessive skin irritation develops
- Condition worsens
- Symptoms persist for longer than 7 days
- Symptoms clear up and reoccur within a few days

If pregnant or breast-feeding, 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.

Caution: This product contains natural rubber latex which may cause allergic reactions.

Directions

Adults and children 12 years of age and over:

- Clean and dry affected area
- Remove patch from film
- Apply to affected area no more than 3 to 4 times daily for 7 days
- Remove patch from skin after at most 8 hours of application
- **Children under 12 years of age:** Consult a doctor

Other Information

- Avoid storing product in direct sunlight
- Protect from excessive moisture

Inactive Ingredients

Butylated hydroxytoluene, Methylparaben, Polysorbate 80, Castor Oil, D-Sorbitol Solution, Concentrated Glycerin, Dihydroxyaluminum Aminoacetate, Disodium Edetate Hydrate, Carboxymethylcellulose sodium, Kaolin, Titanium Dioxide, Sodium Polyacrylate, Aloe Vera Gel, Gelatin, Nikasol TS-620, Tartaric Acid, Nonylic acid vanillyamide, Purified water

PRINCIPAL DISPLAY PANEL

NDC: 81877-601-15

MCM
Topical Gel Patch

(L-Menthol 76.8 mg - Methyl Salicylate 57.6 mg - DL-Camphor 96.0 mg)

Instant Pain Relief

JOINT AND MUSCLE PAIN - SPRAINS - BACKACHE

Forreal Pharmaceuticals LLC
YOUR SOLUTION TO BETTER HEALTHCARE

(5 patches per pouch-3 pouches) **15 Patches**

MCM TOPICAL GEL PATCH

l-menthol patch

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81877-601
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOMENTHOL (UNII: BZ1R15MTK7) (LEVOMENTHOL - UNII:BZ1R15MTK7)	LEVOMENTHOL	76.8 mg
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	57.6 mg
CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	96.0 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CASTOR OIL (UNII: D5340Y2I9G)	
SORBITOL SOLUTION (UNII: 8KW3E207O2)	
GLYCERIN (UNII: PDC6A3C0OX)	

DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
KAOLIN (UNII: 24H4NWX5CO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM POLYACRYLATE (8000 MW) (UNII: 285CYO341L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GELATIN (UNII: 2G86QN327L)	
NICOTINATE ETHANOLAMINE (UNII: 71P617JXF6)	
TARTARIC ACID (UNII: W4888I119H)	
NONIVAMIDE (UNII: S846B891OR)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81877-601-15	3 in 1 POUCH	01/23/2023	
1		5 in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/23/2023	

Labeler - FORREAL PHARMACEUTICALS LLC (118029197)

Revised: 1/2023 FORREAL PHARMACEUTICALS LLC