MENTHOL PAIN RELIEF GEL PATCH- menthol pain relief gel patch patch
ONE2ZEE LIMITED LIABILITY COMPANY

Menthol Pain Relief Gel Patch

Active Ingredient

Menthol 5%

Purpose

Topical Anesthetic

Use

Temporarily relieves minor aches and pain of muscles and joints accociated with, simple backache, arthritis, strains, bruises and sprains

Warnings

For external use only

Do not use:

- more than 1 patch on your body at a time
- on cut, irritated or swollen skin
- on puncture wounds or damaged skin
- for more than one week without consulting a doctor
- with heating pad
- on a child under 12 yeas of age with arthritis-like conditions

When using this product:

- use only as directed.
- read and follow all directions and warnings on this label
- rare cases of serious burns have been reported with products of this type.
- do not apply to wounds or damaged, broken or irritated skin
- do not allow contact with eyes and mucous membranes
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not use at the same time as other topical analgesics
- dispose of used patch in manner that always keeps product away from children and pets
- used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch
- a transient burning sensation may occur upon application but generally disappears in several days

- if a severe burning sensation occurs, discontinue use immediately.
- discontinue use at least 1 hour before a bath or shower.
- do not use immediately after a bath or shower.

Stop use and ask a doctor if:

condition worsens

redness is present over the affected area

excess skin irritation occurs

symptoms persist for more than 7 days or clear up and occur again within a few days

you experience signs of skin injury such as pain, swelling, or blistering where the product was applied

if pregnanat or breast feeding, ask a health professional before use.

keep out of reach of children and pets

if swallowed, get medical help or contact a Poison Control Center right away

Directions:

Adult and children over 12years:
- Clean and dry affected area
- remove backing from patch by firmly grasping both ends and gently pulling until back separates in middle
- carefully remove smaller portion of backing from the patch and apply exposed portion of patch to affected area
- do not wear a patch for more than 8 hours
- apply affected area no more than 3 times daily
- **children 12 years or younger:** ask a doctor

Other Information:

Store at room temperature 20-25^{0}C (68-77^{0}F)

Questions? call toll-free 1-844-912-4012

Inactive Ingredients:

Alpha Tocopherol, Aluminum Sulphate, Borax, Carbomer, Colloidal Silicon Dioxide, DMDM Hydantoin, Glycerin, Kaolin, Polyacrylic Acid, Polyvinyl Alcohol, Polyvinylpyrrolidone , Propylene Glycol, Purified Water, Sodium Carboxymethyl Cellulose, Sodium Ethylenediaminetetraacetic Acid, Sodium Polyacrylate, Sorbitol, Sorbitol Monooleate , Tartaric Acid & Titanium Dioxide, Paraffin

Package Label Box

MENTHOL PAIN RELIEF GEL PATCH

menthol pain relief gel patch patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:55629-025
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	50 mg

Inactive Ingredients	
Ingredient Name	**Strength**
ALPHA-TOCOPHEROL (UNII: H4N855PNZ1)	

ALUMINUM GLYCINATE (UNII: 1K713C615K)	
ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0)	
ALUMINUM SULFATE (UNII: 34S289N54E)	
CARBOMER 934 (UNII: Z135WT9208)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERIN (UNII: PDC6A3C0OX)	
KAOLIN (UNII: 24H4NWX5CO)	
POLYACRYLIC ACID (250000 MW) (UNII: 9G2MAD7J6W)	
POLYVINYL ALCOHOL (100000 MW) (UNII: 949E52Z6MY)	
POVIDONE K27 (UNII: H7AGY1OJO8)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
MAGNESIUM DISODIUM EDTA (UNII: NDT563S5VZ)	
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)	
SORBITOL MONOOLEATE (UNII: 658271J00C)	
TARTARIC ACID (UNII: W4888I119H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PARAFFIN (UNII: I9O0E3H2ZE)	

Product Characteristics

Color	white	**Score**	
Shape	RECTANGLE	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55629-025-15	3 in 1 BOX	03/04/2025	
1		5 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M	03/04/2025	

Labeler - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Registrant - ONE2ZEE LIMITED LIABILITY COMPANY (078656111)

Establishment

Name	Address	ID/FEI	Business Operations
DR. SABHARWAL'S WOUND CARE		862184668	manufacture(55629-025)

Revised: 3/2025

ONE2ZEE LIMITED LIABILITY COMPANY