

**MENTHOL 5% HYDROGEL- menthol, unspecified form patch**  
**Unexo Life Sciences, Private Limited**

*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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**MENTHOL 5% HYDROGEL PATCH**

***Drug Facts***

**Active Ingredient**

Menthol 5%

**Purpose**

Topical Analgesic

**Use**

For temporary relief of minor aches and pains of muscles and joints: arthritis, simple backache, bursitis, tendonitis, muscle strains, muscle sprains, bruises and cramps

**Warnings**

***For external use only***

**When using this product**

- Use only as directed
- Rare cases of serious burns have been reported with products of this type
- Don't bandage tightly or use with a heating pad
- Avoid contact with eyes or mucous membranes
- Don't apply to wounds or damaged skin
- Do not use at the same time as other topical analgesics

**Stop use and consult a doctor if**

- Condition worsens
- redness is present
- Irritation develops
- 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 pregnant or breastfeeding,** ask a health professional before use

**Keep Out of Reach of Children.** Do not use on infants. If swallowed, seek medical

help or contact a Poison Control Centre right away.

### **Directions**

- Adults and children 12 years of age and over: Carefully remove backing from patch. Apply sticky side of patch to affected area. Wear one patch up to 8 hours. Repeat as necessary, but no more than 3 times daily. Discard patch after single use. Reseal pouch after opening. Children under 12 years of age consult a physician.

### **Other Information**

Store at room temperature below 86°F (30°C)

### **Inactive Ingredients**

acrylates copolymer, alcohol, carboxymethylcellulose sodium, edetate Disodium, dihydroxyaluminium aminoacetate, glycerine, kaolin, methylparaben, polysorbate 80, polyvinyl alcohol, propylparaben, PVP, sodium polyacrylate, sorbitan oleate, sorbitol, tartaric Acid, titanium Dioxide, water

Manufactured in India By:  
Unexo Life Sciences Pvt. Ltd.  
B-16, Sector 4, Bawana Industrial Area,  
Delhi - 110039 (INDIA)

### **PRINCIPAL DISPLAY PANEL - 5 Patch Pouch Carton**

NDC 71391-127-05

UNEXO'S MENTHOL 5%  
HYDROGEL PATCH

5% Menthol

BACK & LARGE AREAS

Targeted, Long-Lasting  
Pain Relief

TOPICAL ANALGESIC

- Adhesive Fabric Patch
- No-Mess Application
- Single Use

5  
PATCHES  
7.87 IN. X 3.93 IN. (20 cm x 10 cm)

Compare to Extra Strength  
Icy Hot® Medicated Patch  
active ingredient\*



GLUE

NDC 71391-127-05

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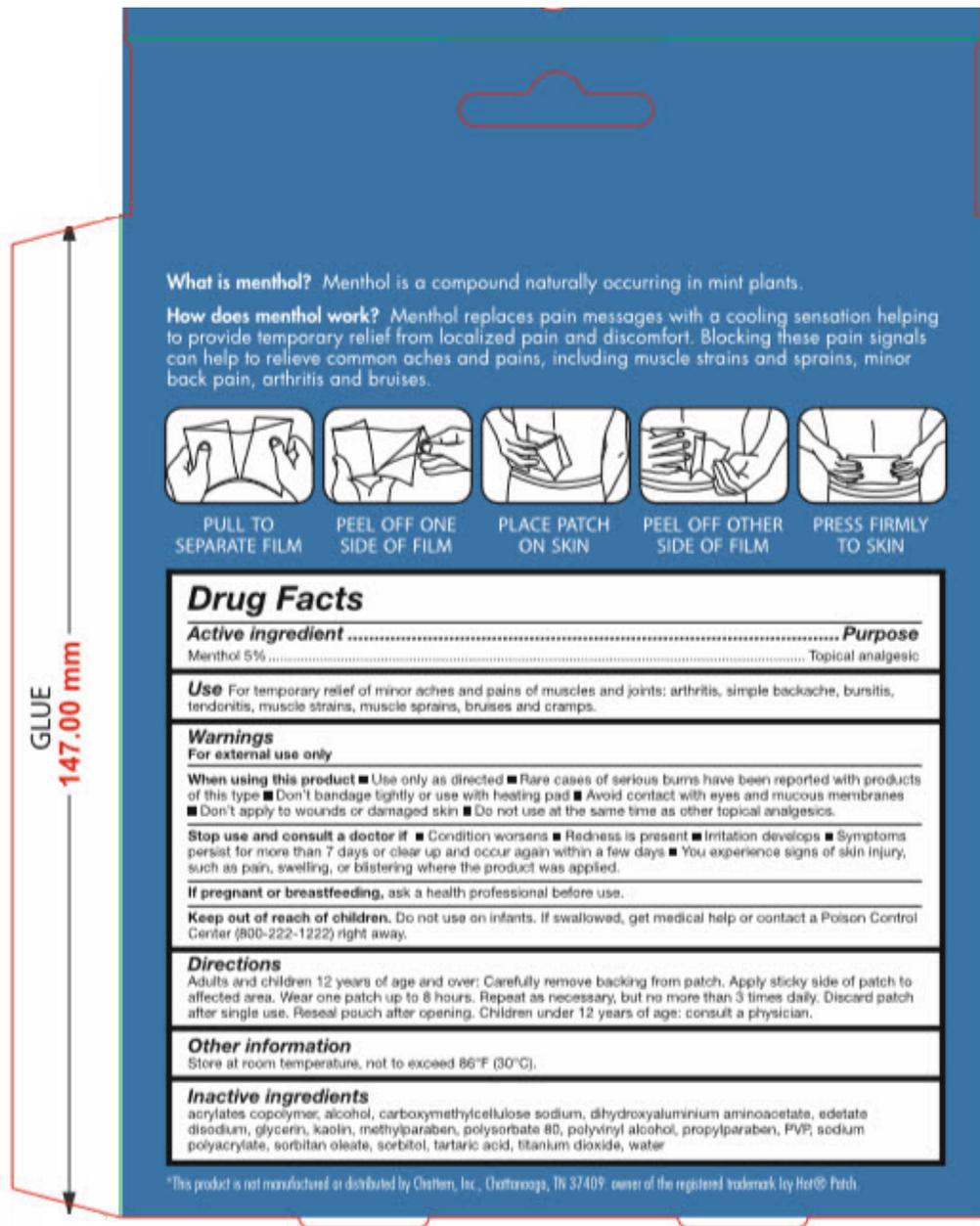
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Email: [info@unexopharma.com](mailto:info@unexopharma.com)  
NC/DL-378-A&U

LOT  
EXP

GLUE



## MENTHOL 5% HYDROGEL

menthol, unspecified form patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71391-127
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)	MENTHOL, UNSPECIFIED FORM	600 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>Butyl acrylate/methyl methacrylate/methacrylic acid copolymer (18000 MW)</b> (UNII: JZ1374NL9E)	
<b>Alcohol</b> (UNII: 3K9958V90M)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>Edetate disodium</b> (UNII: 7FLD91C86K)	
<b>Dihydroxyaluminum aminoacetate</b> (UNII: DO250MG0W6)	
<b>Glycerin</b> (UNII: PDC6A3C00X)	
<b>Kaolin</b> (UNII: 24H4NWX5CO)	
<b>Methylparaben</b> (UNII: A218C7HI9T)	
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)	
<b>Polyvinyl alcohol, unspecified</b> (UNII: 532B59J990)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>Povidone, unspecified</b> (UNII: FZ989GH94E)	
<b>Sodium polyacrylate (2500000 MW)</b> (UNII: 05115JNI2J)	
<b>Sorbitan monooleate</b> (UNII: 06XEA2VD56)	
<b>Sorbitol</b> (UNII: 506T60A25R)	
<b>Tartaric acid</b> (UNII: W4888I119H)	
<b>Titanium dioxide</b> (UNII: 15FIX9V2JP)	
<b>Water</b> (UNII: 059QF0KO0R)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71391-127-05	5 in 1 POUCH; Type 0: Not a Combination Product	10/01/2020	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	10/01/2020	

**Labeler** - Unexo Life Sciences, Private Limited (872260479)

## Establishment

Name	Address	ID/FEI	Business Operations
Unexo Life Sciences, Private Limited		872260479	MANUFACTURE(71391-127)

Revised: 1/2022

Unexo Life Sciences, Private Limited