THE BLACK PATCH- menthol patch Carbon Innovation, Inc.

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.

THE BLACK PATCH

Drug Facts

Active ingredient (in each patch)

Menthol 4%

Purpose

Topical analgesic

Uses

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises, and sprains.

Warnings

For external use only

When using this product

- use only as directed
- avoid contact with the eyes
- do not apply to wounds or damaged skin
- do not bandage tightly

Stop use and ask a doctor if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Directions

- Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: Consult a doctor.

Inactive ingredients

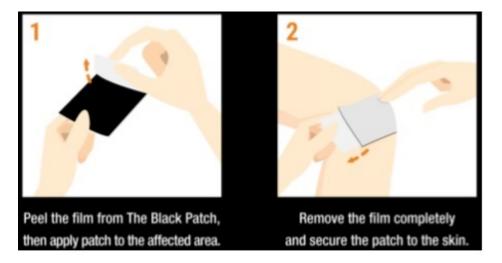
activated charcoal, disodium EDTA, ethanol, gelatin, glycerin, polysorbate 80, polyvinyl alcohol, salt, sodium polyacrylate, tartaric acid, water

Questions or Comments?

1-800-254-5041

HYDROGEL PAIN RELIEF PATCH with MENTHOL

- Soothing relief for painful joints and muscles
- Lasts up to 8 hours
- Just peel and stick
- Contains activated charcoal for smoother skin!



Care Instructions

- The Thydrogel must contact the skin for best results. Clean the skin of oil, dirt, lotions, etc. and dry completely.
- It is sometimes helpful to use medical tape around the edges or a tension bandage to hold the patch securely in place.
- The Black Patch is designed to apply easily and remove residue-free. However, due to heat, excessive moisture, or other factors, some hydrogel residue may transfer.
- If residue transfers onto the skin or clothing, simply wash off with warm water or in the laundry.
- The Black Patch is proudly made in America with natural, food grade ingredients. However, it's not edible so keep it out of reach of small children.

Manufactured by

Carbon Innovation

600 Business Park Dr Lincoln, CA 95648

Packaging

OUTER BOX LABEL



INNER PACKAGE LABEL



THE BLACK PATCH

menthol patch

Product Information

	Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71948-101
l	Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	4 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
ACTIVATED CHARCO AL (UNII: 2P3VWU3H10)				
EDETATE DISO DIUM ANHYDRO US (UNII: 8 NLQ36 F6 MM)				
ALCOHOL (UNII: 3K9958V90M)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POLYVINYL ALCOHOL/POLYVINYL ACETATE COPOLYMER (8:1; 50000 MW) (UNII: 8K8B5SD7ZR)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM POLYACRYLATE (2500000 MW) (UNII: 05I15JNI2J)				
TARTARIC ACID (UNII: W48881119H)				
WATER (UNII: 059QF0KO0R)				

Product Characteristics				
Color	black, white (black and white)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:71948-101-05	5 in 1 PACKAGE	12/30/2017		
1		0.348 g in 1 PATCH; Type 0: Not a Combination Product			
2	NDC:71948-101-10	10 in 1 BOX	12/30/2017		
2		5 in 1 PACKAGE			
2		0.348 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 not final	part348	12/30/2017		

Labeler - Carbon Innovation, Inc. (080987228)

Establishment				
Name	Address	ID/FEI	Business Operations	
Carbon Innovation, Inc.		080987228	manufacture(71948-101)	

Revised: 12/2017 Carbon Innovation, Inc.