TOPLAST COOL MENTHOL 2PERCENT- menthol patch
Icure Pharmaceutical Inc, Wanju Factory

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.

Drug Facts

ACTIVE INGREDIENTS

Menthol 2%

INACTIVE INGREDIENTS

Glycerin, Propylene Glycol, Sodium Polyacrylate, Polyacrylic Acid, Gelatin, Carboxymethylcellulose Sodium, Polyvinyl Alcohol, Titanium Oxide, Tartaric Acid, Polysorbate 80, Sorbitan Monooleate, Disodium Edetate Hydrate, Dihydroxyaluminum Aminoacetate, Water

PURPOSE

Topical Analgesic

WARNINGS

For external use only

Do not use
■ On wounds or damaged skin

Ask a doctor or pharmacist before use if you are allergic to any active or inactive ingredients

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When using this product
■ Use only as directed ■ Read and follow all directions and warnings on this label ■ Do not allow contact with the eyes and mucous membranes or rashes ■ Do not bandage tightly or apply local heat (such as heating pads) to the area of use

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Stop use and ask a doctor if
■ Condition worsens ■ Rash, itching or excessive skin irritation develops ■ Symptoms persist for more than 7 days or reoccur within a few days interval

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If pregnant 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

Uses

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

Directions

Adult and children 12 years of age and over :
■ Clean and dry affected area ■ Peel film from patch and apply to the skin (see illustration) ■ Use 1 patch for up to 12 hours
Children under 12 years of age : Consult a physician

Other Information

■ Store at room temperature 68° to 77°F (20° to 25°C) ■ Store in a clean, dry place out of direct sunlight ■ Protect from excessive moisture

Questions or Comments

■ Visit us at : icure.co.kr/en ■ Contact us : icurepharm@icure.co.kr

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

TOPLAST COOL MENTHOL 2PERCENT
menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:73279-0013
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	150 mg

Inactive Ingredients	
Ingredient Name	**Strength**
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Gelatin (UNII: 2G86QN327L)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Tartaric Acid (UNII: W4888I119H)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Dihydroxyaluminum Aminoacetate (UNII: DO250MG0W6)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:73279-0013-2	2 in 1 CARTON	07/01/2020	
1	NDC:73279-0013-1	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 not final	part348	07/01/2020	

Labeler - Icure Pharmaceutical Inc, Wanju Factory (695687612)

Registrant - Icure Pharmaceutical Inc, Wanju Factory (695687612)

Establishment

Name	Address	ID/FEI	Business Operations
Icure Pharmaceutical Inc, Wanju Factory		695687612	manufacture(73279-0013)