

TOPLAST COOL AND HOT MENTHOL 1.25PERCENT PLUS CAPSAICIN 0.025PERCENT-menthol, capsaicin 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 1.25%

Capsicum extract 0.025% as Capsaicin

INACTIVE INGREDIENTS

Glycerin, Propylene Glycol, Sodium Polyacrylate, Gelatin, Polyvinylpyrrolidone, Carboxymethylcellulose Sodium, Polyvinyl Alcohol, Kaolin, Titanium Oxide, Tartaric Acid, Disodium Edetate Hydrate, Polysorbate 80, Sorbitan Monooleate, 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

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 ■ 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 ■ Rash, itching or excessive skin irritation develops ■ Symptoms persist for more than 7 days or reoccur within a few days interval

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) ■ Apply to affected area not more than 3 to 4 times daily ■ Suggested duration of use for patch is upto 8 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 AND HOT MENTHOL 1.25PERCENT PLUS CAPSAICIN

0.025PERCENT

menthol, capsaicin patch

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73279-0016
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	87.5 mg
Capsaicin (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	Capsaicin	1.75 mg

Inactive Ingredients

Ingredient Name	Strength
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Gelatin (UNII: 2G86QN327L)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
Kaolin (UNII: 24H4NWX5CO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
Tartaric Acid (UNII: W4888I119H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
Dihydroxyaluminum Aminoacetate (UNII: DO250MG0W6)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73279-0016-2	2 in 1 CARTON	07/01/2020	
1	NDC:73279-0016-1	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(73279-0016)

Revised: 7/2020

Icure Pharmaceutical Inc, Wanju Factory