

**TOPLAST COOL AND HOT MENTHOL 5PERCENT 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.*

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**Drug Facts**

**ACTIVE INGREDIENTS**

Menthol 5%

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**

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**Do not use**

■ On wounds or damaged skin

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**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 ■ Discontinue use at least 1 hour before a bath or shower ■ Do not use immediately after a bath or shower

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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



## 0.025PERCENT

menthol, capsaicin patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73279-0018
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Menthol</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	Menthol	350 mg
<b>Capsaicin</b> (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	Capsaicin	1.75 mg

### Inactive Ingredients

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

### Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:73279-0018-2	2 in 1 CARTON	07/01/2020	
1	NDC:73279-0018-1	5 in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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(73279-0018)

Revised: 7/2020

Icure Pharmaceutical Inc, Wanju Factory