

# **TOPLAST PAIN RELIEF LIDOCAINE 4PERCENT PLUS MENTHOL 1PERCENT- lidocaine, 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.*

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## **Drug Facts**

### **ACTIVE INGREDIENTS (in each patch)**

Lidocaine 4%  
Menthol 1%

### **INACTIVE INGREDIENTS**

Glycerin, D-Sorbitol Solution, Propylene Glycol, Sodium Polyacrylate, Polyacrylic Acid, Urea, Carboxymethylcellulose Sodium, Gelatin, Kaolin, Titanium Oxide, Tartaric Acid, Dihydroxyaluminum Aminoacetate, Methylparaben, Polysorbate 80, Sorbitan Oleate, Disodium Edetate Hydrate, Propylparaben, Water

### **PURPOSE**

Topical Anesthetic  
Topical Analgesic

### **WARNINGS**

#### **For external use only**

Safety Warning : Prior to using the product, conduct a skin patch test on your forearm to assess sensitivity and/or allergic reactions

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#### **Do not use**

■ More than 1 patch on your body at a time ■ On the cut, irritated, swollen or puncture wounds ■ For more than one week without consulting a doctor

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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 ■ Do not bandage tightly or apply local heat (such as heating pads) to the area of use ■ Do not use at the same time as other topical analgesics ■ Make sure to dispose the used patch away from children and pets, as used ones still contain the drug that can cause serious adverse effects on them if they chew or ingest the patch

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**Stop use and ask a doctor if**

■ Condition worsens ■ Redness is present ■ Irritation develops ■ Symptoms persist for more than 7 days or recur ■ Skin swells or blisters where the product was applied

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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

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**Uses**

For temporary relief of minor pain

**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 at a time and do not use for more than 12 hours

**Children under 12 years of age :** consult a physician

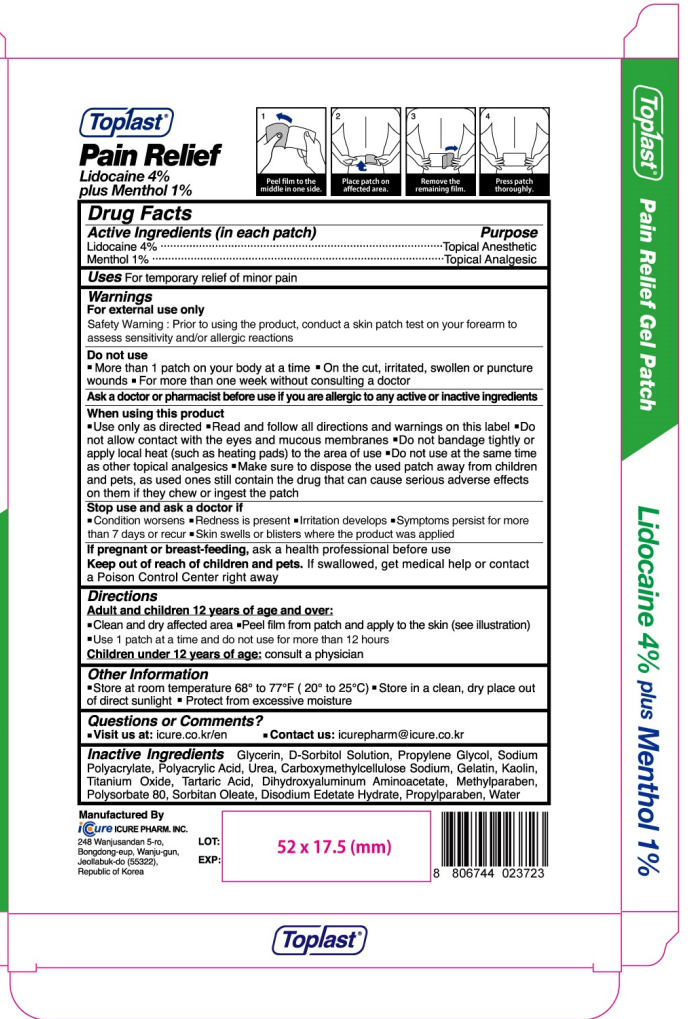
**Other Information**

■ 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](http://icure.co.kr/en) ■ Contact us : [icurepharm@icure.co.kr](mailto:icurepharm@icure.co.kr)

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**



# TOPLAST PAIN RELIEF LIDOCAINE 4PERCENT PLUS MENTHOL 1PERCENT

lidocaine, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73279-0004
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Lidocaine (UNII: 98PI200987) (LIDOCAINE - UNII:98PI200987)		Lidocaine	240 mg
Menthol (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)		Menthol	60 mg
Inactive Ingredients			
Ingredient Name			Strength
Glycerin (UNII: PDC6A3C0OX)			

<b>SORBITOL</b> (UNII: 506T60A25R)
<b>Propylene Glycol</b> (UNII: 6DC9Q167V3)
<b>Urea</b> (UNII: 8W8T17847W)
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)
<b>Gelatin</b> (UNII: 2G86QN327L)
<b>Kaolin</b> (UNII: 24H4NWX5CO)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>Tartaric Acid</b> (UNII: W4888I119H)
<b>Dihydroxyaluminum Aminoacetate</b> (UNII: DO250MGOW6)
<b>Methylparaben</b> (UNII: A2I8C7HI9T)
<b>Polysorbate 80</b> (UNII: 6OZP39ZG8H)
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)
<b>Water</b> (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73279-0004-2	5 in 1 CARTON	07/01/2020	
1	NDC:73279-0004-1	1 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(73279-0004)