

## **TOPLAST HOT CAPSAICIN 0.025PERCENT- 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**

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

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

The image shows the principal display panel for the Toplast Hot Gel Patch Capsaicin 0.025% package. The panel is divided into several sections:

- Top Left:** Toplast logo and iCure logo.
- Center:** Toplast logo, "Hot Gel Patch" in large red and black text, and "Capsaicin 0.025%" in red text.
- Bottom Left:** Illustration of a human back with a patch applied to the lower back. Below it, a list of benefits: "Thermal Therapeutic Effect", "Simple Backache, Arthritis, Strains, Bruises, Sprains", and "Resealable Pouch".
- Bottom Center:** "10 PATCHES" in large text, with "3 1/4" X 5 1/2" (10 cm X 14 cm)" and "MADE IN KOREA" below it.
- Bottom Right:** A list of features: "Easy to apply & remove", "Lasts up to 8 hours", "Flexible & Adhesive", and "Odor-free".
- Right Side:** A vertical red banner with "Toplast HOT Gel Patch Capsaicin 0.025%" written vertically.
- Bottom Right (Detailed Panel):** A detailed panel with the following sections:
  - Toplast HOT Gel Patch Capsaicin 0.025%** with a 4-step illustration: 1. Pull apart, 2. Peel off one side of the film, 3. Peel off the remaining film, 4. Press patch thoroughly.
  - Drug Facts:** Active Ingredients (in each patch): Capsaicin extract 0.025% as Capsaicin. Purpose: Topical Analgesic.
  - Uses:** For temporary relief of minor aches and pains of muscles and joints associated with: Simple backache, Arthritis, Strains, Bruises, Sprains.
  - 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.
  - 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](http://icure.co.kr/en). Contact us: [icurepharm@icure.co.kr](mailto:icurepharm@icure.co.kr).
  - 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.
  - Manufactured By:** iCure ICURE PHARM, INC. 248 Wanjungdan 5-ro, Bongdong-eup, Wanjung-gun, Jeollabuk-do 55329, Republic of Korea. LOT: EXP:

**TOPLAST HOT CAPSAICIN 0.025PERCENT**

capsaicin patch

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73279-0019
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
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: W4888119H)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
Polysorbate 80 (UNII: 6OZP39ZG8H)	
SORBITAN MONOLEATE (UNII: 06XEA2VD56)	
Dihydroxyaluminum Aminoacetate (UNII: DO250MG0W6)	
Water (UNII: 059QF0K00R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73279-0019-2	2 in 1 CARTON	07/01/2020	
1	NDC:73279-0019-1	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(73279-0019)