

## **TAKAHI HOT MEDICATED PLASTER- camphor plaster**

### **Indo Abadi Sari Makmur, PT**

*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.*

-----

**Indo Abadi Sari Makmur, PT**

### **Active Ingredients**

Camphor (Synthetic) 2.59%

Capsicum Oleoresin 3.29%

### **Purpose**

Camphor (Synthetic) Topical Analgesic

Capsicum Oleoresin Topical Analgesic

### **Uses**

For temporary relief of minor aches and pains of muscles and joints associated with arthritis, simple backache, strains, sprains, and bruises.

### **DIRECTIONS**

- Wash the skin with soap and water; and dry it well.
- Remove the covering material from the adhesive side of the plaster.
- Place the plaster on the aching spot and press it to the skin until it sticks.
- After use, remove the plaster by taking it at one corner and tear it off. If there are any places of plaster remaining, they can be removed easily by rubbing the spot with alcohol or spirit. The plaster should be worn for 2 or 3 days. In extreme case, a second one may be applied.

### **Warnings**

External Use Only. Do not use for children below 12 years of age.

### **Warnings**

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

### **Stop Use and Ask a Doctor If**

- the situation gets worst.

- symptoms persist after 7 days use.
- if undesirable effects are encountered.
- if you are pregnant.
- you are allergic to lactation.

## Other Information

Store at temperature not exceeding 30°C (86°F).

## Manufactured by

INDO ABADI SARIMAKMUR, PT.  
Dusun Ngablak, Ds. Gempolkurung, No. 168M  
Kec. Menganti, Kab. Gresik - Jawa Timur  
Indonesia

## Inactive Ingredients

BORNEOL, NATURAL LATEX RUBBER, ROSIN, SILICON DIOXIDE, GLYCEROL ESTER OF HYDROGENATED ROSIN, LANOLIN, GINGER OIL, HEXANE

## Drug Facts



# TAKAHI HOT MEDICATED PLASTER

camphor plaster

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70815-003
<b>Route of Administration</b>	TRANSDERMAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CAMPHOR (SYNTHETIC)</b> (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) - UNII:5TJD82A1ET)	CAMPHOR (SYNTHETIC)	2.59 g in 100 g
<b>CAPSICUM OLEORESIN</b> (UNII: UW86K581WY) (CAPSICUM OLEORESIN - UNII:UW86K581WY)	CAPSICUM OLEORESIN	3.29 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
<b>BORNEOL</b> (UNII: M89NIB437X)	
<b>NATURAL LATEX RUBBER</b> (UNII: 2LQ0UUW8IN)	
<b>ROSIN</b> (UNII: 88S87KL877)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>GLYCEROL ESTER OF HYDROGENATED ROSIN</b> (UNII: XH62RP786N)	
<b>LANOLIN</b> (UNII: 7EV65EAW6H)	
<b>GINGER OIL</b> (UNII: SAS9Z1SVUK)	
<b>HEXANE</b> (UNII: 2DDG612ED8)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70815-003-10	1 in 1 BOX	07/31/2016	
1		0.3 g in 1 PATCH; Type 1: Convenience Kit of Co-Package		
2	NDC:70815-003-25	1 in 1 BOX	07/31/2016	
2		0.6 g in 1 PATCH; 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	07/31/2016	

