

**CAPSIMIDE- capsaicin 0.025% topical patch patch**  
**Sola Pharmaceuticals**

*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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**Capsimide Patch**

***Active Ingredients***

Capsaicin 0.025%

***Purpose***

Topical Analgesic

***Uses***

Temporarily relieves minor pain.

***Warnings***

**For external use only**

***Do not use***

- more than one patch on your body at a time
- on cut, irritated or swollen skin
- on puncture wounds
- for more than one week without consulting a doctor
- if you are allergic to any active or inactive ingredients
- if pouch is damaged or opened

***When using this product***

- use only as directed
- read and follow all directions and warnings on this carton
- do not allow contact with the eyes
- do not use at the same time as other topical analgesics
- do not bandage tightly or apply local heat (such as heating pads) to the area of use
- do not microwave
- dispose of used patch in a manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.

**Stop use and ask a doctor if**

- condition worsens
- redness is present
- irritation develops
- symptoms persist for more than 7 days or clear up and occur again within a few days
- you experience signs of skin injury, such as pain, swelling or blistering where the product was applied.

**If pregnant or breast-feeding**

ask a health professional before use.

**Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away.

**Directions**

Adults and children 12 years of age and over: Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use. Children under 12 years of age: consult a physician.

**Other Information**

Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture.

**Other Ingredients**

Glycerin, Sodium polyacrylate, Dihydroxyaluminum aminoacetate, Edetate disodium, Kaolin, Carboxymethylcellulose sodium, Titanium dioxide, L-Tartaric acid, Polyacrylic acid, Propylene glycol, Polysorbate 80, Isopropyl Myristate, Hydroxyacetophenone, Water, and PVP

**Questions or comments?**

866-747-7365

Manufactured for:

SOLA PHARMACEUTICALS LLC

Baton Rouge, LA 70810

[www.solameds.us](http://www.solameds.us)

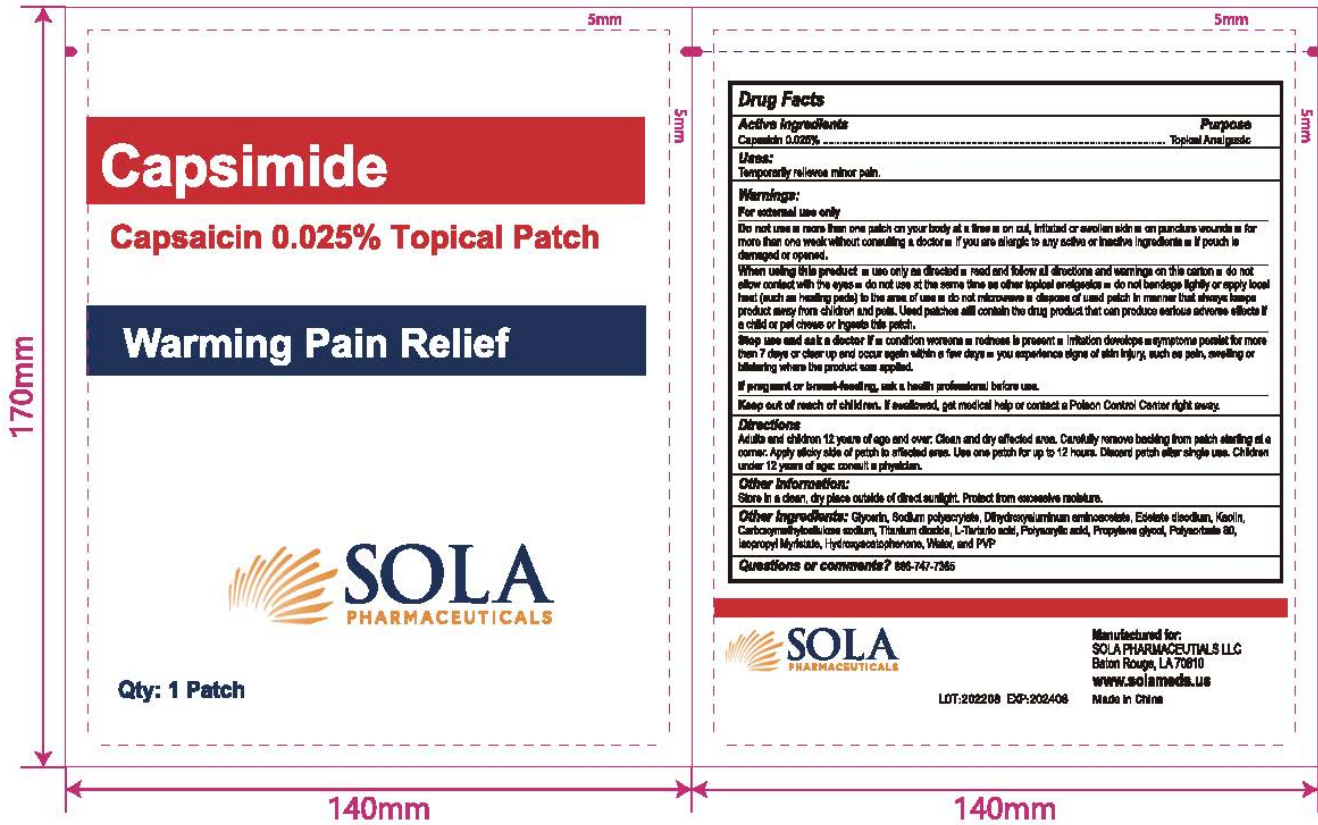
Made in China

Capsimide Patch

NDC 70512-016-10

Qty: 10 Patches

(1 per pouch) x 10





Drug Facts	
<b>Active Ingredients</b>	<b>Purpose</b>
Capsaicin 0.025%	Topical Analgesic
<b>Uses:</b>	
Temporarily relieves minor pain.	
<b>Warnings:</b>	
For external use only.	
Do not use more than one patch on your body at a time. Do not use on cut, irritated or swollen skin. Do not use on puncture wounds. Do not use more than one week without consulting a doctor. If you are allergic to any active or inactive ingredients. If pouch is damaged or opened.	
When using this product: use only as directed. Read and follow all directions and warnings on this carton. Do not allow contact with the eyes. Do not use at the same time as other topical analgesics. Do not bandage tightly or apply local heat (such as heating pads) to the area of use. Do not microwave. Dispose of used patch in manner that always keeps product away from children and pets. Used patches still contain the drug product that can produce serious adverse effects if a child or pet chews or ingests this patch.	
Stop use and ask a doctor if: condition worsens; redness is present; irritation develops; symptoms persist for more than 7 days or clear up and occur again within a few days; you experience signs of skin injury, such as pain, swelling or blistering where the product was applied.	
If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
Adults and children 12 years of age and over: Clean and dry affected area. Carefully remove backing from patch starting at a corner. Apply sticky side of patch to affected area. Use one patch for up to 12 hours. Discard patch after single use. Children under 12 years of age: consult a physician.	
<b>Other information:</b>	
Store in a clean, dry place outside of direct sunlight. Protect from excessive moisture.	
<b>Other ingredients:</b> Glycerin, Sodium polyacrylate, Dihydroxyaluminum aminoacetate, Edible disodium, Kaolin, Carboxymethylcellulose sodium, Titanium dioxide, L-Tartaric acid, Polyacrylic acid, Propylene glycol, Polysorbate 80, Isopropyl Myristate, Hydroxyacetophenone, Water, and PVP.	
<b>Questions or comments?</b> 866-747-7365	

## CAPSIMIDE

capsaicin 0.025% topical patch patch

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70512-016
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CAPSAICIN (UNII: S07O44R1ZM) (CAPSAICIN - UNII:S07O44R1ZM)	CAPSAICIN	0.025 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
WATER (UNII: 059QF0KO0R)	
DIHYDROXYALUMINUM AMINOACETATE (UNII: DO250MG0W6)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
KAOLIN (UNII: 24H4NWX5CO)	

<b>CARBOXYMETHYLCELLULOSE SODIUM</b> (UNII: K679OBS311)	
<b>SODIUM POLYACRYLATE (8000 MW)</b> (UNII: 285CYO341L)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TARTARIC ACID</b> (UNII: W4888I119H)	
<b>POLYACRYLIC ACID (8000 MW)</b> (UNII: 73861X4K5F)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Product Characteristics

<b>Color</b>		<b>Score</b>	
<b>Shape</b>	RECTANGLE	<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70512-016-10	10 in 1 BOX	09/07/2022	
1		9 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/07/2022	

**Labeler** - Sola Pharmaceuticals (080121345)

Revised: 9/2022

Sola Pharmaceuticals